

Schedule of Accreditation



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|---|---|
| Organisation Name | St James's Hospital |
| Trading As | SJH Centre for Laboratory Medicine and Molecular Pathology |
| INAB Reg No | 327MT |
| Contact Name | Fiona Kearney |
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| Website | http://www.stjames.ie |
| Accreditation Standard | EN ISO 15189 |
| Standard Version | 2012 |
| Date of award of accreditation | 28/10/2014 |
| Scope Classification | Microbiology and virology |
| Scope Classification | Blood Transfusion Science |
| Scope Classification | Haematology |
| Scope Classification | Immunology |
| Scope Classification | Histopathology and cytopathology |
| Scope Classification | Chemical pathology |
| Services available to the public ¹ | |

¹ Refer to document on interpreting INAB Scopes of Accreditation

| Sites from which accredited services are delivered | | |
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| (the detail of the accredited services delivered at each site are on the Scope of Accreditation) | | |
| | | |
| | Name | Address |
| 1 | Head Office | Laboratory Medicine Directorate, James's Street, Dublin, D8 |

Scope of Accreditation

Head Office

Blood Transfusion Science

Category: A

| Medical pathology field - Test | Test/assay | Specimen Type | Equipment/Technique | Method (CE/Non-CE/In house developed/based on standard method) | Range of measurement | Std. ref & SOP |
|--|-----------------------------|------------------|-----------------------------------|--|----------------------|--------------------------------------|
| 1020 Transfusion science - .01 Blood grouping including ABO, Rh(D) and other antigens by manual methods | Blood Grouping (ABO & Rh D) | EDTA Whole Blood | 1. Tube technique 2. Gel Cards | CE Marked | Not applicable | 1. SOP BT 3.0001 2. SOP BT 3.0002 |
| 1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods | Blood Grouping (ABO & RhD) | | Ortho Vision Max Swift Analyser | CE marked/Automated Based on standard method | Not applicable | SOP BT 3.0057 |
| 1020 Transfusion science - .03 Blood group antibody screen | Antibody Screening | | Ortho Vision Max Swift Analyser | CE marked/Automated Based on standard method | Not applicable | SOP BT 3.0057 |
| | | Plasma | Manual Gel Cards | CE Marked | Not applicable | SOP BT 3.0005 |
| 1020 Transfusion science - .04 Identification of blood group antibodies | Antibody identification | EDTA whole blood | Ortho Vision Max Swift Analyser | CE marked/Automated | Not applicable | SOP BT 3.0062 |

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| | | | | Based on standard method | | |
| | | Plasma | Manual Gel cards | CE Marked | Not applicable | SOP BT 3.0016 |
| 1020 Transfusion science - .05 Cross match compatible donor units | Compatability analysis for the release of compatible blood by electronic means | | LIS / Electronic Issue | CE Marked | Not applicable | SOP BT 3.0053 |
| | Crossmatching | | 1. Manual Tubes 2. Manual Gel Cards | CE Marked | Not applicable | 1.SOP BT 3.0012 2.SOP BT 3.0009 |
| 1020 Transfusion science - .06 Red cell phenotyping | Antigen Typing | Red Blood Cells | 1. Manual Tubes 2. Manual Gel Cards | CE Marked | Not applicable | 1 & 2.SOP BT 3.0027 |
| | Antigen typing - Rh Phenotype | EDTA whole blood Red cells | Ortho Vision Max Swift Analyser | CE marked/Automated Based on standard method | Not applicable | SOP BT 3.0057 |
| 1020 Transfusion science - .09 Direct antiglobulin test | Direct Antiglobulin Test | | Ortho Vision Max Swift Analyser | CE marked/Automated Based on standard method | Not applicable | SOP BT 3.0061 |
| | Direct Coombes Testing | Red Blood Cells | Manual Gel Cards | CE Marked | Not applicable | SOP BT 3.0018 |

The hospital blood bank has been assessed and is competent to comply with Articles 14 and 15 of the EU Directive 2002/98/EC (S.I. 360/2005 and S.I. 547/2006)

Category: A

| Medical pathology field - Test | Test/assay | Specimen Type | Technique | Equipment/Range of Measurement | Method (CE/Non-CE/In house developed/based on standard method) | Std. Ref & SOP | |
|---|--|----------------|--|--------------------------------|--|--------------------------|-------------|
| 1061 Clinical Chemistry - .01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies | Alanine Amino Transferase (ALT) **1,2,3,4 | Serum / Plasma | Alanine Aminotransferase acc. to IFCC without pyridoxal phosphate activation | Cobas 8000 | CE Marked | LM-BIO-0243 | |
| | Alkaline Phosphatase **1,2,3,4 | | Colourimetric Assay | Cobas 8000 | CE Marked | LM-BIO-0243 | |
| | Amylase **1,2,3,4 | | Enzymatic colorimetric assay acc. to IFCC | Cobas 8000 | CE Marked | LM-BIO-0243 | |
| | | Urine | Enzymatic colorimetric assay acc. to IFCC | Cobas 8000 | CE Marked | LM-BIO-0243 | |
| | Asparate Amino Transferase (AST) **1,2,3,4 | Serum / Plasma | Asparate Amino Transferase acc. to IFCC without PP activation | Cobas 8000 | CE Marked | LM-BIO-0243 | |
| | Bicarbonate **1,2,3,4 | | Enzymatic with PEP | Cobas 8000 | CE Marked | LM-BIO-0243 | |
| | Bilirubin Direct **1,2,3,4 | | Diazo Method | Cobas 8000 | CE Marked | LM-BIO-0243 | |
| | Bilirubin Total **1,2,3,4 | | Colourimetric Diazo Method | Cobas 8000 | CE Marked | LM-BIO-0243 | |
| | Calcium **1,2,3,4 | | NM-BAPTA | Cobas 8000 | CE Marked | LM-BIO-0243 | |
| | | | Urine | NM-BAPTA | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Calculated TIBC | | Serum / Plasma | Calculation | LIS Interface | Based on Standard Method | LM-BIO-0243 |
| | Chloride **1,2,3,4 | | | Indirect ISE | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | | Urine | | Indirect ISE | Cobas 8000 | CE Marked | LM-BIO-0243 |

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| Cholesterol **1,2,3,4 | Serum / Plasma | Enzymatic Colorimetric assay | Cobas 8000 | CE Marked | LM-BIO-0243 |
| Corrected Calcium | | Calculation | LIS Interface | Based on Standard Method | LM-BIO-0243 |
| Creatine Kinase (CK) **1,2,3,4 | | IFCC UV-test | Cobas 8000 | CE Marked | LM-BIO-0243 |
| Creatinine **1,2,3,4 | | Enzymatic Colorimetric assay | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Urine | Enzymatic Colorimetric assay | Cobas 8000 | CE Marked | LM-BIO-0243 |
| Creatinine Clearance | Serum/Plasma & Urine | Calculation | LIS Interface | Based on Standard Method | LM-BIO-0243 |
| Cystatin C *1,2,3,4 | Serum/Plasma | Particle Enhanced Immunoturbidometric Assay | Cobas 8000 | CE Marked | LM-BIO-0243 |
| EGFR | Serum / Plasma | Calculation | LIS Interface | Based on Standard Method | LM-BIO-0243 |
| Fractionated Excretion of Sodium | Serum/Plasma & Urine | Calculation | LIS Interface | Based on Standard Method | LM-BIO-0243 |
| Gamma Glutamyl Transferase (GGT) **1,2,3,4 | Serum / Plasma | Enzymatic Colorimetric assay | Cobas 8000 | CE Marked | LM-BIO-0243 |
| Glucose **1,2,3,4 | CSF | Enzymatic reference method with hexokinase | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Fluoride Oxalate | Enzymatic reference method with hexokinase | Cobas 8000 | CE Marked | LM-BIO-0243 |
| High Density Lipoprotein (HDL) **1,2,3,4 | Serum / Plasma | Enzymatic | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | | UV Assay | Cobas 8000 | CE Marked | LM-BIO-0243 |
| Lipoprotein a *1,2,3,4 | Serum/Plasma | Particle Enhanced Immunoturbidometric Assay | Cobas 8000 | CE Marked | LM-BIO-0243 |
| Low Density Lipoprotein (LDL) | Serum / Plasma | Calculation | LIS Interface | Based on Standard Method | LM-BIO-0243 |
| Magnesium **1,2,3,4 | | Colourimetric Assay | Cobas 8000 | CE Marked | LM-BIO-0243 |

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|---|---------------------------------|---------------------|-----------------------------------|---------------|--------------------------|-------------|
| | | Urine | Colourimetric Assay | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Microalbumin/Creatinine Ratio | | Calculation | LIS Interface | Based on Standard Method | LM-BIO-0243 |
| | Non HDL Cholesterol | Serum / Plasma | Calculation | LIS Interface | Based on Standard Method | LM-BIO-0243 |
| | NT-Pro-BNP **1,2,3,4 | | Immunoassay sandwich principle | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Phosphate - Inorganic **1,2,3,4 | | Molybdate UV | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | | Urine | Molybdate UV | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Potassium **1,2,3,4 | Serum / Plasma | Indirect ISE | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | | Urine | Indirect ISE | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Protein/Creatinine Ratio | | Calculation | LIS Interface | Based on Standard Method | LM-BIO-0243 |
| | Sodium **1,2,3,4 | Serum / Plasma | Indirect ISE | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | | Urine | Indirect ISE | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Total:HDL Cholesterol Ratio | Serum / Plasma | Calculation | LIS Interface | Based on Standard Method | LM-BIO-0243 |
| | Triglycerides **1,2,3,4 | | Enzymatic Colourimetric Test | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Troponin T hs **1,2,3,4 | EDTA Plasma | Immunoassay sandwich principle | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Urea **1,2,3,4 | Serum / Plasma | Urease + Glutamate Dehydrogenase | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | | Urine | Urease + Glutamate Dehydrogenase | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Uric Acid **1,2,3,4 | Serum / Plasma | Enzymatic Colourimetric Test | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | | Urine | Enzymatic Colourimetric Test | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Vitamin D **1,2,3,4 | Serum/Li-Hep Plasma | Immunoassay competitive principle | Cobas 8000 | CE Marked | LM-BIO-0243 |
| 1061 Clinical Chemistry - .02 Proteins, quantitative analysis | Albumin **1,2,3,4 | Serum / Plasma | Colourimetric Assay | Cobas 8000 | CE Marked | LM-BIO-0243 |

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| | C Reactive Protein (CRP) **1,2,3,4 | | Particle Enhanced Immunoturbidometric Assay | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Calprotectin **1,2,4 | Faeces | ELISA | Allegria | CE Marked | LM-BIO-0253 |
| | Microalbumin **1,2,4 | Urine | Immunoturbidimetric Assay | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Protein - Total **1,2,3,4 | CSF | Turbidimetric Method | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | | Serum / Plasma | Colourimetric Assay | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | | Urine | Turbidimetric Method | Cobas 8000 | CE Marked | LM-BIO-0243 |
| 1061 Clinical Chemistry - .08 Haemo-related pigments and precursors | ALA & PBG **1,4 | | Ionic column with colour reaction (Recipe™ kit) | UV 1700 | CE Marked | LM-BIO-0263 |
| | Erythrocyte Porphyrins **1,4 | EDTA Whole Blood | Scanning Fluorimeter | Shimadzu RF6000 | In-house developed | LM-BIO-0270 |
| | Plasma Porphyrins **1,4 | Plasma | Scanning Fluorimeter | Shimadzu RF6000 | In-house developed | LM-BIO-0270 |
| | Porphyrins (Uroporphyrin I, Uroporphyrin III, Heptaporphyrin, Coproporphyrin I, Coproporphyrin III, Duetero, Meso, Proto) **1,4 | Faeces | HPLC | Shimadzu HPLC-2030C Plus/ | In-house developed | LM-BIO-0269 |
| | | Urine | HPLC | Shimadzu HPLC-2030C Plus/ | In-house developed | LM-BIO-0269 |
| 1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring | Amikacin **1,2,3,4 | Serum / Plasma | KIMS | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Carbamazepine **1,2,3,4 | | KIMS | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Digoxin **1,2,3,4 | Serum/Plasma | Competitive Immunoassay | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Gentamicin **1,2,3,4 | | Homogenous enzyme immunoassay system | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Inflectra ADA/Infliximab ADA **1,2,4 | EDTA Plasma or Serum | ELISA | Dynex DS2 | CE Marked | LM-BIO-0259 |

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| | Inflectra/Infliximab **1,2,4 | | ELISA | Dynex DS2 | CE Marked | LM-BIO-0258 |
| | Lithium **1,2,3,4 | Serum | Colourimetric Assay | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Methotrexate **1,2,3,4 | Serum/Plasma | Homogenous enzyme immunoassay system | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Phenytoin **1,2,3,4 | Serum / Plasma | KIMS | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Posaconazole **1,2,3,4 | Serum/Plasma | LC-MS-MS | API4000 | CE Marked | LM-BIO-0255 |
| | Theophylline **1,2,3,4 | Serum / Plasma | KIMS | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Valproate **1,2,3,4 | | Homogenous enzyme immunoassay system | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Vancomycin **1,2,3,4 | Serum | KIMS | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Voriconazole **1,2,3,4 | Serum/Plasma | LC-MS-MS | API4000 | CE Marked | LM-BIO-0255 |
| 1061 Clinical Chemistry - .14 Alcohol for non-legal purposes | Ethanol *1,2,3,4 | Serum / Plasma | Enzymatic Method with Alcohol Dehydrogenase | Cobas 8000 | CE Marked | LM-BIO-0243 |
| 1061 Clinical Chemistry - .15 Drugs for toxicological purposes | Paracetamol **1,2,3,4 | | Enzymatic | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Salicylate **1,2,3,4 | | Enzymatic | Cobas 8000 | CE Marked | LM-BIO-0243 |
| 1061 Clinical Chemistry - .20 Hormones | 17-Alpha OH Progesterone **1,2,3,4 | Serum | LC-MS-MS | ABSciex Triple Quad 4500 | CE Marked | LM-BIO-0254 |
| | ACTH **1,2,3,4 | EDTA Plasma | Immunoassay sandwich principle | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Aldosterone **1,2,3,4 | | Competitive Immunoassay Chemiluminescence | IDS-ISYS | CE Marked | LM-BIO-0247 |
| | Androstendione **1,2,3,4 | Serum | LC-MS-MS | ABSciex Triple Quad 4500 | CE Marked | LM-BIO-0254 |
| | Anti-Mullerian Hormone **1,2,3,4 | Serum/Plasma | Immunoassay sandwich principle | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | C Peptide **1,2,3,4 | Serum / Plasma | Immunoassay sandwich principle | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Cortisol **1,2,3,4 | | Competitive immunoassay | Cobas 8000 | CE Marked | LM-BIO-0243 |

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| DHEAS **1,2,3,4 | Serum | LC-MS-MS | ABSciex Triple Quad 4500 | CE Marked | LM-BIO-0254 |
| Direct Renin **1,2,3,4 | EDTA Plasma | Sandwich Immunoassay Chemiluminescence | IDS-ISYS | CE Marked | LM-BIO-0247 |
| Follicle Stimulating Hormone (FSH) **1,2,3,4 | Serum / Plasma | Immunoassay sandwich principle | Cobas 8000 | CE Marked | LM-BIO-0243 |
| Free T4 **1,2,3,4 | Serum/Plasma | Competitive Immunoassay | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Serum/Plasma | Competitive Immunoassay | Abbott Alinity | CE Marked | LM-BIO-0266 |
| Growth Hormone **1,2,3,4 | Serum | Sandwich Chemiluminescence | IS-ISYS | CE Marked | LM-BIO-0247 |
| hCG **1,2,3,4 | Serum / Plasma | Immunoassay sandwich principle | Cobas 8000 | CE Marked | LM-BIO-0243 |
| Insulin **1,2,3,4 | | Immunoassay sandwich principle | Cobas 8000 | CE Marked | LM-BIO-0243 |
| Insulin-Like Growth Factor 1 (IGF1) **1,2,3,4 | Serum | Chemiluminescence | IS-ISYS | CE Marked | LM-BIO-0247 |
| Leutenising Hormone (LH) **1,2,3,4 | Serum / Plasma | Immunoassay sandwich principle | Cobas 8000 | CE Marked | LM-BIO-0243 |
| Oestradiol **1,2,3,4 | | Competitive Immunoassay | Cobas 8000 | CE Marked | LM-BIO-0243 |
| Parathyroid Hormone (PTH) **1,2,3,4 | Serum | Immunoassay sandwich principle | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Serum/Plasma | Sandwich Immunoassay | Cobas e411 | CE Marked | LM-BIO-0260 |
| Procollagen III **1,2,3,4 | Serum | Competitive radioimmunoassay | Wizard 2470 Gamma Counter | CE Marked | LM-BIO-0256 |
| Progesterone **1,2,3,4 | Serum / Plasma | Competitive Immunoassay | Cobas 8000 | CE Marked | LM-BIO-0243 |
| Prolactin - post fractionated **1,2,3,4 | Serum/Plasma | PEG Precipitation | Cobas 8000 | CE Marked | LM-BIO-0243 |
| Prolactin **1,2,3,4 | Serum / Plasma | Immunoassay sandwich principle | Cobas 8000 | CE Marked | LM-BIO-0243 |

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| | Sex Hormone Binding Globulin (SHBG) **1,2,3,4 | | Immunoassay sandwich principle | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | T3 Total **1,2,3,4 | | Competitive Immunoassay | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | T4 Total **1,2,3,4 | | Competitive Immunoassay | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Testosterone **1,2,3,4 | Serum | LC-MS-MS | ABSciex Triple Quad 4500 | CE Marked | LM-BIO-0254 |
| | Thyroid Receptor Antibodies (TRAB) **1,2,3,4 | | Competitive Immunoassay | Brahms Kryptor Gold | CE Marked | LM-BIO-0271 |
| | Thyroid Stimulating Hormone (TSH) **1,2,3,4 | Serum/Plasma | Sandwich Immunoassay | Abbott Alinity | CE Marked | LM-BIO-0266 |
| | Thyroid Stimulating Hormone (TSH) **1,2,3,4 | Serum | Immunoassay sandwich principle | Cobas 8000 | CE Marked | LM-BIO-0243 |
| 1061 Clinical Chemistry - .40 Iron studies | Iron **1,2,3,4 | Serum / Plasma | Colourimetric Assay | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Transferrin Saturation | | Calculation | LIS Interface | Based on Standard Method | LM-BIO-0243 |
| | UIBC **1,2,3,4 | Serum/Plasma | Direct Determination with FerroZine | Cobas 8000 | CE Marked | LM-BIO-0243 |
| 1061 Clinical Chemistry - .47 Vitamin assays | 25-Hydroxyvitamin D3 and D2 **1,2,3,4 | Serum | LC-MS-MS | API 4000 | CE Marked | LM-BIO-0074 |
| | Vitamin A (Retinol) | | Extraction method using HPLC | Shimadzu HPLC-2030C Plus | CE Marked | LM-BIO-0030 |
| | Vitamin E (Tocopherol) | | Extraction method using HPLC | Shimadzu HPLC-2030C Plus | CE Marked | LM-BIO-0030 |
| 1061 Clinical Chemistry - .50 Protein and peptide tumour markers | Alpha Fetoprotein (AFP) **1,2,3,4 | Serum / Plasma | Immunoassay sandwich principle | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | CA125 **1,2,3,4 | | Immunoassay sandwich principle | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | CA15.3 **1,2,3,4 | | Immunoassay sandwich principle | Cobas 8000 | CE Marked | LM-BIO-0243 |

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| | CA19.9 **1,2,3,4 | | Immunoassay sandwich principle | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Calcitonin **1,2,3,4 | | Immunoassay sandwich principle | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | CEA **1.2.3.4 | | Immunoassay sandwich principle | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Chromogranin A *1,2,3,4 | Serum | Automated Immunofluorescent Assay | Kryptor Gold/ | CE Marked | LM-BIO-0271 |
| | PSA Free **1,2,3,4 | Serum / Plasma | Immunoassay sandwich principle | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | PSA Total **1,2,3,4 | | Immunoassay sandwich principle | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Thyroglobulin **1,2,3,4 | Serum | Immunoassay sandwich principle | Brahms Kryptor Gold | CE Marked | LM-BIO-0271 |
| 1061 Clinical Chemistry - .52 Collagen cross-link markers | CTX (Beta-CrossLaps) **1,2,3,4 | Serum/Plasma | Immunoassay sandwich principle | Cobas e411 | CE Marked | LM-BIO-0260 |
| | Osteocalcin **1,2,3,4 | | Immunoassay sandwich principle | Cobas e411 | CE Marked | LM-BIO-0260 |
| | P1NP **1,2,3,4 | | Immunoassay sandwich principle | Cobas e411 | CE Marked | LM-BIO-0260 |
| 1061 Clinical Chemistry - .60 Glycohaemoglobins | Haemoglobin A1c **1,2,4 | EDTA Whole Blood | HPLC | Adams A1c HA-8180V | CE Marked | LM-BIO-0249 |
| 1061 Clinical Chemistry - .63 Breath tests | Urea Breath Test | Breath | Non-Dispersive Ion-Selective Infrared Spectrometry | Kibion Dynamic Base UBT Analyser | CE Marked | LM-BIO-0273 |
| 1061 Clinical Chemistry - .71 Faecal Immunochemical test | Faecal Occult Blood **4 | Faeces | Immunochemical Lateral Flow device | Biohit Colonview, Positive/Negative | CE Marked | LM-BIO-0267 |
| 1061 Clinical Chemistry - .75 Malabsorption tests, not otherwise specified | Faecal Elastase **1,2,4 | | ELISA | Dynex DS2 | CE Marked | LM-BIO-0069 |
| 1061 Clinical Chemistry - .85 Anti-thyroglobulin antibodies | Thyroglobulin Antibodies **1,2,3,4 | Serum | Competitive Immunoassay | Brahms Kryptor Gold | CE Marked | LM-BIO-0271 |
| 1061 Clinical Chemistry - .99 Miscellaneous tests | ACE **1,2,3,4 | Serum / Plasma | Enzymatic | Cobas 8000 | CE Marked | LM-BIO-0243 |

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| | Cholinesterase **1,2,3,4 | | Colourimetric Assay | Cobas 8000 | CE Marked | LM-BIO-0243 |
| | Haemochromatosis Genotyping (Detection of C282Y and H63D mutations) | EDTA and Buccal swabs | Allelic discrimination assay end point PCR using Taqman probes on a real time PCR platform | 7500 Fast real time PCR system | In-house developed | LM-BIO-0075 |
| | Osmolality **1,2,3,4 | Serum/Li-Hep Plasma/Urine | Freezing-point depression | Advanced Instruments OsmoPro and Fiske3320 | CE Marked | LM-BIO-0248 |
| | Procalcitonin **1,2,3,4 | Serum/Plasma | Immunoassay Sandwich | Cobas 8000 | CE Marked | LM-BIO-0243 |
| 1064 Molecular genetics - .01 Screening for unidentified pathogenic variant(s) | MLPA amplification of LDLR gene | EDTA whole blood or buccal swab | MLPA fragment analysis | Thermocycler and AB 3130 Sanger sequencer | CE Marked | LM-BIO-0265 |
| | Sequence analysis of CPOX gene associated with hereditary coproporphyrinemia (HCP) | EDTA whole blood | Sanger Sequencing | Thermocycler and gel electrophoresis | In house developed | LM-BIO-0262 |
| | Sequence analysis of HMBS gene associated with acute intermittent porphyria (AIP) | | Sanger Sequencing | Thermocycler and gel electrophoresis and Sanger sequencer | In house developed | LM-BIO-0264 |
| | Sequence analysis of PPOX gene associated with variegate porphyria (VP) | | Sanger Sequencing | Thermocycler and gel electrophoresis | In house developed | LM-BIO-0264 |
| | Sequence analysis of the TTR gene associated with transthyretin (ATTR) cardiac amyloidosis | | Sanger Sequencing | Thermocycler and gel electrophoresis | In house developed | LM-BIO-0262 |
| Allelic Discrimination Assay for APOE rs7412 Genotyping | Allelic Discrimination | | 7500 Fast real time PCR system | In house developed | LM-BIO-0272 | |
| 1064 Molecular genetics - .02 Assay for identified pathogenic variant(s) | Sequence analysis of the TTR gene associated with transthyretin (ATTR) cardiac amyloidosis | | Sanger Sequencing | Thermocycler and gel electrophoresis and Sanger Sequencing | In house developed | LM-BIO-0262 |

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| 1065 Molecular pathology - .01 Assay for somatic variants in DNA sequence(s) | Detection of pathogenic variants in Familial Hypercholesterolaemia using smMIPS NGS | Peripheral blood | smMIP library preparation followed by next generation sequencing | Hamilton Starlet ML 4CH Automated Library preparation system, Ion Torrent (Life technologies) | Non-CE, based on standard method | VP-MOLB-0005 M-CMD-0076 |
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The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratory's approved and documented procedures.

Note 1 - Range may be extended for the test

Note 2 – New parameters/tests may be added

Note 3 – New matrices may be added

Note 4 – Changes to equipment/kits where the underlying methodology does not change

For further details please refer to the laboratory's 'List of flexible scope changes', available directly from the laboratory.

Category: A

| Medical pathology field - Test | Test/Assay | Specimen Type | Technique | Range of Measurement/Equipment | Method (CE/Non-CE/In house developed/based on standard method) | Std. Ref & SOP |
|--|--|---------------|---|---|--|-----------------|
| 1030 Haematology - .01 Blood counts | Full Blood Count Including WBC, and Nucleated RBC Quantitation **1,2,3,4 | EDTA Blood | Electrical impedance cell counting and sizing, fluorescent flow cytometry and spectrophotometry | Sysmex XN10 / XN20 | CE Marked | HAEM-LM-RH-0026 |
| 1030 Haematology - .02 Visual examination of blood films | Blood Film Examination **1,2,3,4 | | Automated digital morphology system with operator reclassification and result validation | SP10 Blood Film Stainer Sysmex DI-60 | Based on Standard Method | HAEM-LM-RH-0006 |
| | | | Manual | SP10 Blood Film Stainer Microscope | Based on Standard Method | HAEM-LM-RH-0006 |
| 1030 Haematology - .03 Erythrocyte sedimentation rate | Erythrocyte Sedimentation Rate (ESR) **1,3,4 | | Westergren Sedimentation Method | Starrsed Interliner Automated ESR Analyser | CE Marked | HAEM-LP-RH-0016 |
| 1030 Haematology - .06 Automated reticulocyte counts | Reticulocyte Count **1,3,4 | | Electrical impedance cell counting and sizing, fluorescent flow cytometry and spectrophotometry | Sysmex XN10 / XN20 | CE Marked | HAEM-LM-RH-0026 |
| 1030 Haematology - .09 Examination of malarial parasites | Malaria Screen **1,3,4 | | Manual microscopy | Microscope, Fields Stain A & B, Giemsa. P. falciparum, P.vivax, P.ovale, P.malariae, P knowlesi | Based on standard method | HAEM-LM-RH-0012 |
| | Screening Test for Malarial HRP-2 Antigen and LDH **1,3,4 | | EDTA blood | Malarial HRP-2 Antigen and LDH detection using the Malaria CareStart Kit | P. falciparum; P. vivax or ovale or malariae or Knowlesi; P. falciparum or mixed infection | CE Marked |
| 1030 Haematology - .20 Bone marrow examination | Bone Marrow Iron Stain **3,4 | Bone Marrow | Cytochemical Stain | Manual | Based on Standard Method | HAEM-LM-SH-0002 |

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| | MGG Stain for Bone Marrow Aspirates **3,4 | | Cytochemical Stain | IUL Polystainer | CE Marked | HAEM-LM-SH-0009, HAEM-LM-SH-0012 |
| 1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia | Haemoglobin fractions **1,3,4 | EDTA Blood | Capillary Electrophoresis | Sebia Capillarys 2 Flex Piercing Analyser | CE Marked | HAEM-LP-SH-0028 |
| | Hb H Inclusions **3,4 | | Supra Vital Stain | Manual | Based on Standard Method | HAEM-LM-SH-0065 |
| | Hemoglobin fractions **1,3,4 | | HPLC | Biorad Variant II | CE Marked | HAEM-LP-SH-0012, HAEM-MP-SH-0001 |
| | IEF of Hb **3,4 | | Isoelectric Focussing | Multiphor Electrophoresis | CE Marked | HAEM-LM-SH-0062 |
| | Sickle Screen **3,4 | | Solubility Test | Manual | CE Marked | HAEM-LM-SH-0058 |
| 1030 Haematology - .35 Tests to investigate haemolysis | Dapsone Screen (Heinz Body Screen) **3,4 | EDTA Blood | Supra Vital Stain | Manual | Based on Standard Method | HAEM-LM-SH-0051 |
| | Haptoglobin **1,3,4 | | Radial Immunodiffusion | Manual | CE marked | HAEM-LM-SH-0052 |
| | Membrane Screen **1,3,4 | | Flow Cytometry | BD Facscanto II | In-house developed | HAEM-LM-SH-0109 |
| | PNH Screening GLY-A,CD59, FLAER, CD45, CD24, CD14, CD15, CD64 `** 1,3,4 | | Flow Cytometry | BD FACS Canto II | In-House Developed | HAEM-LM-SH-0105 |
| | Urinary Haemosiderin **4 | Urine | Cytochemical Stain | Manual | Based on Standard Method | HAEM-LM-SH-0053 |
| 1030 Haematology - .36 Screening tests for G6Pd | Glucose-6-phosphate Dehydrogenase (G6PD) Screen **4 | EDTA Blood | Fluorescent Spot Test | Manual | CE Marked | HAEM-LM-SH-0069A |
| 1030 Haematology - .40 Limited haemostasis related tests | Anticoagulant Monitoring - Apixaban **1,2,4 | Sodium Citrate | Photo-optical detection | ACL TOP 750 | CE Marked | HAEM-LM-COAG-0124 |
| | Anticoagulant Monitoring - Dabigatran **1,2,4 | | Photo-optical detection | ACL TOP 750 | CE Marked | HAEM-LM-COAG-0121 |

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| Anticoagulant Monitoring - Rivaroxaban **1,2,4 |
| Anticoagulant Monitoring: Argatroban **1,2,4 |
| Anticoagulant Monitoring: Edoxaban |
| Antithrombin Assay **1,2,4 |
| APCR Assay **1,2,4 |
| Assessment of VWF multimers in plasma by electrophoresis |
| Correction Tests **1,2,4 |
| Factor II:C Assay **1,2,4 |
| Factor IX Inhibitor Assay **1,2,4 |
| Factor IX:C Assay **1,2,4 |
| Factor V:C Assay **1,2,4 |
| Factor VII:C Assay **1,2,4 |
| Factor VIII Inhibitor Assay **1,2,4 |
| Factor VIII:C Assay **1,2,4 |
| Factor X:C Assay **1,2,4 |
| Factor XI:C Assay**1,2,4 |
| Factor XII:C Assay **1,2,4 |
| Factor XIII Assay **1,2,4 |

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| Photo-optical detection | ACL TOP 750 | CE Marked | HAEM-LM-COAG-0125 |
| Photo-optical Detection | ACL TOP 750 | CE Marked | HAEM-LM-COAG-0102 |
| Photo-optical Detection | ACL Top | CE Marked | HAEM-LM-COAG-0140 |
| Photo-optical Detection | ACL TOP 750 | CE Marked | HAEM-LM-COAG-0089 |
| Photo-optical Detection | ACL TOP 750 | CE Marked | HAEM-LM-COAG-0092 |
| Electrophoresis | SEBIA:HYDRASYS 2 | CE Marked | HAEM-LM-COAG-0133 |
| Photo-optical Detection | ACL TOP 550 | Based on Standard Method | HAEM-LM-COAG-0021 |
| Photo-optical Detection | ACL TOP 750 | CE Marked | HAEM-LM-COAG-0120 |
| Photo-optical Detection | ACL TOP 750 | Based on Standard Method | HAEM-LM-COAG-0131 |
| Photo-optical Detection | ACL TOP 750 | CE Marked | HAEM-LM-COAG-0120 |
| Photo-optical Detection | ACL TOP 750 | CE Marked | HAEM-LM-COAG-0120 |
| Photo-optical Detection | ACL TOP 750 | CE Marked | HAEM-LM-COAG-0120 |
| Photo-optical Detection | ACL TOP 750 | Based on Standard Method | HAEM-LM-COAG-0115 |
| Photo-optical Detection | ACL Top | CE Marked | HAEM-LM-COAG-0120 |
| Photo-optical Detection | ACL TOP 750 | CE Marked | HAEM-LM-COAG-0120 |
| Photo-optical Detection | ACL TOP 750 | CE Marked | HAEM-LM-COAG-0120 |
| Photo-optical Detection | ACL TOP 750 | CE Marked | HAEM-LM-COAG-0120 |
| Latex Immunoassay | ACL TOP 750 | CE Marked | HAEM-LM-COAG-0087 |

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| | FVIII Chromogenic assay **1,2,4 | | Photo-optical Detection | ACL TOP 750 | CE Marked | HAEM-LM-COAG-0134 | |
| | Heparin Induced Thrombocytopenia Screen: IgG ELISA **1,3,4 | Serum | ELISA | Memmery Hot Air Oven Labsystems Biotek 800 TS Microplate Reader | CE Marked | HAEM-LM-COAG-0085 | |
| | Lupus Anticogulant Screen **1,2,4 | Sodium Citrate | Photo-optical Detection | ACL TOP 750 | CE Marked | HAEM-LM-COAG-0090 | |
| | Measurement of Emicizumab level *1,2,4 | | Photo-optical detection | ACL Top | In house developed | HAEM-LM-COAG-0141 | |
| | Protein C Assay **1,2,4 | | Photo-optical Detection | ACL TOP 750 | CE Marked | HAEM-LM-COAG-0091 | |
| | Protein S Assay (Free Antigen) **1,2,4 | | Latex Immunoassay | ACL TOP 750 | CE Marked | HAEM-LM-COAG-0122 | |
| | VWF:Ag Assay **1,2,4 | | Latex Immunoassay | ACL TOP 750 | CE Marked | HAEM-LM-COAG-0099 | |
| | VWF:CB Assay **1,4 | | ELISA | Labsystems Biotek 800 TS Microplate Reader | CE Marked | HAEM-LM-COAG-0065 | |
| | VWF:FVIII binding assay **1,4 | | Asserachrom VWF:FVIII B ELISA kit | Biotek 800TS microplate reader | CE marked kit | HAEM-LM-COAG-0117 | |
| | VWF:Rco Assay **1,4 | | Photo-optical Detection | Sysmex CS2100i | CE Marked | HAEM-LM-COAG-0100 | |
| 1030 Haematology - .41 General haemostasis related tests | Anticoagulant Drug Monitoring: Heparin Anti Xa Assay **1,2,4 | | | Photo-optical Detection | ACL TOP 750 | CE Marked | HAEM-LM-COAG-0112 |
| | APTT/APTT Ratio **1,2,4 | | | Photo-optical Detection / Calculation | ACL TOP 550 | CE Marked | HAEM-LM-COAG-0077 |
| | D-Dimer **1,2,4 | | Latex Immunoassay | ACL TOP 550 | CE Marked | HAEM-LM-COAG-0123 | |
| | Fibrinogen **1,2,4 | | Photo-optical Detection | ACL TOP 550 | CE Marked | HAEM-LM-COAG-0084 | |
| | Fibrinogen Antigen **1,4 | | Radial Immunodiffusion | Immuno-Viewer Plate Reader | CE Marked | HAEM-LM-COAG-0046 | |
| | Fibrinogen Antigen *1,2,4 | | Latex Immuno-assay | ACL Top | CE kit | HAEM-LM-COAG-0143 | |
| | PT/INR **1,2,4 | | Photo-optical Detection | ACL TOP 550 | CE Marked | HAEM-LM-COAG-0077 | |

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| | Thrombin Time **1,2,4 | | Photo-optical detection | ACL TOP 550 | CE marked kit | HAEM-LM-COAG-0129 |
| 1030 Haematology - .45 Tests of platelet function | Platelet Function Tests **1,2,3,4 | | Photo-optical Detection | Helena Biosciences Aggregation Remote Analyser Module | Based on Standard Method | HAEM-LM-COAG-0032 |
| | Quantitation of Platelet Adenine Nucleotides Using Firefly Luminescence **1,2,3,4 | CTAD | Luminescence | Promega Glomax 20/20 Luminometer | Based on Standard Method | HAEM-LM-COAG-0083 |
| 1030 Haematology - .55 Iron studies | Ferritin **1,2,3,4 | Serum | Chemiluminescent immunometric assay | Siemens Atellica IM | CE Marked Kit | HAEM-LM-NA-0032 |
| 1030 Haematology - .57 Screening test for infectious mononucleosis | Infectious Mononucleosis **1,3,4 | EDTA Blood/serum/plasma | Immunoassay | Test Kit | CE Marked | HAEM-LM-RH-0025 |
| 1030 Haematology - .58 Vitamin B12 and folate (serum and red cell) | B12 **1,2,3,4 | Serum | Chemiluminescent immunometric assay | Siemens Atellica IM | CE Marked Kit | HAEM-LM-NA-0032 |
| | Serum Folate / Folic Acid **1,2,3,4 | | Chemiluminescent immunometric assay | Siemens Atellica IM | CE Marked Kit | HAEM-LM-NA-0032 |
| 1030 Haematology - .62 Plasma viscosity | Plasma Viscosity **1,3,4 | EDTA Blood | Viscometry | Benson Viscometer | CE Marked | HAEM-LP-SH-0010 |
| 1030 Haematology - .70 Immunophenotyping | Acute Leukaemia Panel. Antigens Tested: CD19,CD117,CD45,CD34,CD14,CD64,CD33, CD7,CD13, HLA-DR, CD2, CD10,CD20, CD38,CD56, cMPO, cCD3, nuclear TdT, cCD79a, cCD68, cIgM, CD15,CD36,CD300e,CD4,CD11b, CD61, GLY-A, CD41, CD65,NG2, CD9,CD203c,CD2, CD8,CD3,CD99,CD1a,CD5, cBCL2, cCD61, CD43, CD123,CD21,CD58,CD66 **1,2,3,4 | Bone Marrow Aspirate in RPMI-Heparin or in EDTA. FNA or Fluids in RPMI-Heparin. Edta Blood | Flow Cytometry | BD Facscanto II | In-house developed | HAEM-LM-SH-0110 |
| | B cell Acute Lymphoblastic Minimal Residual Disease detection (B ALL MRD) CD38, CD34, CD10, CD81, CD19, CD20, CD45, CD66c, CD123, CD73, CD304, CD24, CD9, CD15, CD21, CD22, CD33, CD58, CD65, CD66, CD13, NG2, cTdT, cIgM **1,2,3,4 | Bone Marrow Aspirate in RPMI-Heparin or in EDTA, FNA or Fluids in RPMI-Heparin, EDTA Blood | Flow cytometry | BD Facs Canto II | In house developed | HAEM-LM-SH-0117 , HAEM-LM-SH-0113 |
| | Chronic Lymphoproliferative Panel. Antigens Tested: CD5,CD3,CD19,CD45,surface Kappa, surface Lambda, CD38,CD43,CD200, | Bone Marrow Aspirate in RPMI-Heparin or in EDTA. | Flow Cytometry | BD Facscanto II | In-house developed | HAEM-LM-SH-0110 |

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| <p>slgM, FMC7, CD20, CD10, CD22, CD23, CD79b, CD103, CD11c, CD25, CD123, CD49d, ROR1, CD62L, CD7, CD2, CD4, CD26, CD8, TCRαβ, TCRγδ, CD16, CD56, CD57, CD52, CD30, CD9, CD203c, CD33, CD24, CD117, HLA-DR, CD38, CD138, cKappa, cLambda, VS38c **1,2,3,4</p> | <p>FNA or Fluids in RPMI-Heparin. Edta Blood</p> | | | | |
| <p>CSF Immunophenotyping. Antigens Tested: CD7, CD117, CD10, CD34, CD19, CD45, CD3, CD8, CD56, Surface Kappa, Surface Lambda, CD4, CD14, CD38, CD20 **1,2,3,4</p> | <p>CSF in RPMI-Heparin or Transfix</p> | <p>Flow Cytometry</p> | <p>BD Facscanto II</p> | <p>In-house developed</p> | <p>HAEM-LM-SH-0114</p> |
| <p>Detection of Measurable Residual Disease (MRD) by flow cytometry in Acute Myeloid Leukaemia *1,2,3,4</p> | <p>Bone marrow aspirate in RPMI - Heparin or in EDTA. FNA or Fluids in RPMI-Heparin. EDTA Blood.</p> | <p>Flow cytometry/Immunophenotyping</p> | <p>BD Facs Canto II flow cytometers.</p> | <p>In house developed</p> | <p>HAEM-LM-SH-0120</p> |
| <p>Detection of Minimal Residual Disease (MRD) in B Chronic Lymphocytic Leukaemia (B-CLL). Antigens Tested: CD19, CD5, CD3, CD22, CD20, CD79b, CD81, CD43 **1,2,3,4</p> | <p>Bone Marrow Aspirate in RPMI-Heparin or in EDTA. Edta Blood.</p> | <p>Flow Cytometry</p> | <p>BD Facscanto II</p> | <p>In-house developed</p> | <p>HAEM-LM-SH-0113</p> |
| <p>Detection of Minimal Residual Disease (MRD) in Mantle Cell Lymphoma (MCL). Antigens Tested: CD5, CD20, CD23, CD45, CD19, CD62L, CD200, CD3 **1,2,3,4</p> | <p>Bone Marrow Aspirate in RPMI-Heparin or in EDTA, FNA or Fluids in RPMI-Heparin, EDTA Blood</p> | <p>Flow Cytometry</p> | <p>BD Facscanto II</p> | <p>In-house developed</p> | <p>HAEM-LM-SH-0113</p> |
| <p>Detection of TRBC 1. Antigens tested: CD8, CD3, CD2, CD5, CD7, CD4, TCRgd **1,2,3,4</p> | | <p>Flow cytometry</p> | <p>BD Facs Canto II</p> | <p>In house developed</p> | <p>HAEM-LM-SH-0110 , HAEM-VM-SH-0011</p> |
| <p>MDS Ogata and RED score by flow cytometry. Antigens Tested: CD15, CD117, CD34, CD10, CD33, CD45, CD19, CD36, CD71 **1,2,3,4</p> | <p>Bone Marrow Aspirate in RPMI-Heparin or in EDTA</p> | <p>Immunophenotyping/flow cytometry</p> | <p>BD Facs Canto II</p> | <p>In house developed</p> | <p>Haem-LM-SH-0115, Haem-VM-SH-0117</p> |
| <p>T ALL MRD protocol: Antigens Tested: CD99, CD8, CD7, CD34, CD5, CD45, CD4, CD3, cTdT, cCD3 **1,2,3,4</p> | <p>Bone Marrow Aspirate in RPMI-Heparin or in EDTA, FNA or Fluids in</p> | <p>Immunophenotyping/flow cytometry</p> | <p>BD Facs Canto II</p> | <p>Based on standard method (IC-BFM T ALL MRD method)</p> | <p>ALL IC-BFM FLOW SOP 06-2014, Haem-LM-SH-0113</p> |

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| | | RPMI-Heparin, EDTA Blood | | | | |
| | T Cell Enumeration. Antigens Tested: CD19,CD3,CD45 **1,2,3,4 | Bone Marrow Aspirate in RPMI-Heparin or in EDTA. Edta Blood. FNA or Fluids in RPMI-Heparin, EDTA Blood | Flow Cytometry | BD Facscanto II | In-house developed | HAEM-LM-SH-0112 |
| 1030 Haematology - .80 Molecular genetic studies | Copy number variation (CNV) analysis of the F8 and F9 genes. | Blood EDTA | Multiplex Ligation-dependent Probe Amplification (MLPA) | QIASymphony SP, Applied Biosystems Thermal Cycler, Applied Biosystems ABI 3500 Genetic Analyser. | Non-CE. Based on standard method | Std. Ref: • Jan P. Schouten, Cathal J. McElgunn, Raymond Waaijer, Danny Zwijnenburg, Filip Diepvens, Gerard Pals, Relative quantification of 40 nucleic acid sequences by multiplex ligation-dependent probe amplification, Nucleic Acids Research, Volume 30, Issue 12, 15 June 2002, Page e57, SOPs: HAEM-LM-HMD-017, HAEM-LP-HMD-039 |
| | Detection of Factor V Leiden variant **3,4 | EDTA | Real Time PCR | Cepheid GeneXpert (Absent, Heterozygous, Homozygous) | CE Marked | HAEM-LM-COAG-0138 |
| | Detection of Prothrombin G20210A variant **3,4 | | Real Time PCR | Cepheid GeneXpert (Absent, Heterozygous, Homozygous) | CE Marked | HAEM-LM-COAG-0138 |
| | DNA sequencing to detect single nucleotide variations and small DNA deletions and duplications within the F8, F9, VWF exons 18- | Blood EDTA | PCR amplification, Sanger Sequencing | QIASymphony SP, Applied Biosystems Thermal Cycler, | In house developed. Based | Std. Ref: Sanger F, Nicklen S, Coulson AR. |

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| 24, VWF exon 28, SERPINC1, MYH9, Fibrinogens (FGA, FGB, FGG) genes. | | | Applied Biosystems ABI 3500 Genetic Analyser JSI Software SeqPatient module | on standard method | DNA sequencing with chain-terminating inhibitors. Proc Natl Acad Sci U S A. 1977;74(12):5463-5467. SOPs: HAEM-LP-HMD-003, HAEM-LP-HMD-04, HAEM-LP-HMD-007, HAEM-LP-HMD-017, HAEM-LP-HMD-020, HAEM-LP-HMD-038, HAEM-LP-HMD-039 |
| F8 Intron 1 assay to detect F8 gene rearrangements involving intron 1 | | F8 Intron 1 PCR by PCR amplification and gel electrophoresis | QIASymphony SP, Applied Biosystem Thermal Cycler, EC 105 Electrophoresis Powerpack, Electrophoresis tank 1-3, UV gel documentation system. | Non-CE. Based on standard method | Std. Ref: • Liu Q, Sommer SS, Biotechniques 1998 25 pp1022-1028. SOPs: HAEM-LP-HMD-006 |
| F8 Intron 22 assay to detect F8 gene rearrangements involving intron 22 | | F8 Intron 22 Inverse PCR by PCR amplification and fragment analysis | QIASymphony SP, Applied Biosystems Thermal Cycler, Applied Biosystems ABI 3500 Genetic Analyser. | Non-CE. Based on standard method | Std. Ref: • Rossetti LC, Radic CP, Larripa IB, De Brasi CD. Clin Chem. 2005 Jul; 51(7):1154-8; • Rossetti LC, Radic CP, Larripa IB, De Brasi CD. J Thromb Haemost. 2008 May; 6(5):830-6 SOPs: |

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| 1030 Haematology - .99 Miscellaneous tests | Cyclosporin assay **1,2,3,4 | Whole Blood EDTA | Chemiluminescent microparticle immunoassay (CMIA) | Abbott Alinity i | CE | HAEM-LM-NA-0036 |
| | Cyclosporine A **1,2,3,4 | EDTA Blood | Chemiluminescent immunometric assay | Siemens Atellica IM | CE Marked Kit | HAEM-LM-NA-0033 |
| | Erythropoietin **1,2,3,4 | Serum | Chemiluminescent Immunometric Assay | Beckman Coulter Access 2 | CE Marked | HAEM-LM-NA-0024 |
| | Homocysteine **1,2,3,4 | EDTA Blood | Chemiluminescent immunometric assay | Siemens Atellica IM | CE Marked Kit | HAEM-LM-NA-0034 |
| | IF (Intrinsic Factor) Antibody **1,2,3,4 | Serum | Chemiluminescent Immunometric Assay | Beckman Coulter Access 2 | CE Marked | HAEM-LM-NA-0024 |
| | Serum Transferrin Receptor **1,2,3,4 | | Chemiluminescent Immunometric Assay | Beckman Coulter Access 2 | CE Marked | HAEM-LM-NA-0024 |
| | Tacrolimus assay **1,2,3,4 | Whole Blood EDTA | Chemiluminescent microparticle immunoassay (CMIA) | Abbott Alinity i | CE | HAEM-LM-NA-0035 |
| 1033 Molecular pathology - .01 Assay for somatic variants in DNA sequence(s) | BCR-ABL1 p190 fusion Detection of rearrangements associated with leukaemia | Bone Marrow | PCR | GeneAmp PCR System 2700 or 2720 (Applied Biosystems) 7500 Real time PCR instrument (Applied Biosystems) | Non-CE Based on standard method | M-CMD-0024 M-CMD-0039 M-CMD-0063 |
| | | Peripheral Blood | PCR | GeneAmp PCR System 2700 or 2720 (Applied Biosystems) 7500 Real time PCR instrument (Applied Biosystems) | Non-CE Based on standard method | M-CMD-0024 M-CMD-0039 M-CMD-0063 |
| | BCR-ABL1 p190 RQ-PCR Monitoring of Transcripts Associated with Leukaemia | Peripheral Blood, bone marrow | PCR | 7500 Real Time PCR System (Applied Biosystems) | Non-CE, Based on standard method | M-CMD-0093 |
| | BCR-ABL1 p210 and p190 RQ-PCR Monitoring of Transcripts Associated with Leukaemia | Bone Marrow | PCR | Hamilton Microlab STAR and 7500 Real Time PCR | Non-CE Based on standard method | M-CMD-0093 |

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| | | | System (Applied Biosystems) | | |
| | Peripheral Blood | PCR | Hamilton Microlab STAR and 7500 Real Time PCR System (Applied Biosystems) | Non-CE Based on standard method | M-CMD-0093 |
| BCR-ABL1 p210 fusion Detection of rearrangements associated with leukaemia | Bone Marrow | PCR | GeneAmp PCR System 2700 or 2720 (Applied Biosystems) 7500 Real time PCR instrument (Applied Biosystems) | Non-CE Based on standard method | M-CMD-0022 M-CMD-0039 M-CMD-0063 |
| | Peripheral Blood | PCR | GeneAmp PCR System 2700 or 2720 (Applied Biosystems) 7500 Real time PCR instrument (Applied Biosystems) | Non-CE Based on standard method | M-CMD-0022 M-CMD-0039 M-CMD-0063 |
| BCR-ABL1 p210 fusion Detection of rearrangements associated with leukaemia | Bone Marrow | PCR | Hamilton Microlab STAR and 7500 Real Time PCR System (Applied Biosystems) | Non-CE Based on standard method | M-CMD-0094 |
| | Peripheral Blood | PCR | Hamilton Microlab STAR and 7500 Real Time PCR System (Applied Biosystems) | Non-CE Based on standard method | M-CMD-0094 |
| BCR-ABL1 RQ-PCR Monitoring of Transcripts Associated with Leukaemia | Bone Marrow | PCR | 7500 Real Time PCR System (Applied Biosystems) | Non-CE Based on standard method | M-CMD-0059 |
| | Peripheral Blood | PCR | 7500 Real Time PCR System (Applied Biosystems) | Non-CE Based on standard method | M-CMD-0059 |
| CALR mutation detection. Detection of mutations associated with myeloproliferative neoplasms. | Bone Marrow | PCR | GeneAmp PCR System 2700 or 2720 (Applied Biosystems) Dyad DNA Engine (Bio-Rad) | Non-CE Based on standard method | M-CMD-0069 |

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| | Peripheral Blood | PCR | GeneAmp PCR System 2700 or 2720 (Applied Biosystems) Dyad DNA Engine (Bio-Rad) | Non-CE Based on standard method | M-CMD-0069 |
| Detection of somatic mutations using a smMIP Panel (MPN Panel) | Peripheral Blood, bone marrow, FFPE tissue | smMIP library preparation with NGS based sequencing | QIASymphony DNA Extraction system, Hamilton Star Automated Library preparation system, Ion Chef, Illumina Next Seq, Thermal cycler | Non-CE, based on standard method | M-CMD-0076 M-CMD-0068 M-CMD-0092 |
| FLT3-ITD mutations Detection of mutations associated with leukaemia | Bone Marrow | PCR | GeneAmp PCR System 2700 or 2720 (Applied Biosystems) X2 Dyad DNA Engine (Bio-Rad) | Non-CE Based on standard method | M-CMD-0030 M-CMD-0031 |
| | Peripheral Blood | PCR | GeneAmp PCR System 2700 or 2720 (Applied Biosystems) X2 Dyad DNA Engine (Bio-Rad) | Non-CE Based on standard method | M-CMD-0030 M-CMD-0031 |
| Immunoglobulin gene rearrangements. Detection of genomic rearrangements associated with leukaemia and lymphoma. | Bone Marrow | PCR | Hamilton Microlab STAR GeneAmp PCR System 2700 or 2720 (Applied Biosystems) 3130xl Genetic Analyser (Applied Biosystems) | CE Based on standard method | M-CMD-0010 M-CMD-0011 M-CMD-0012 M-CMD-0013 |
| | Fresh Biopsy | PCR | Hamilton Microlab STAR GeneAmp PCR System 2700 or 2720 (Applied Biosystems) 3130xl Genetic Analyser (Applied Biosystems) | CE Based on standard method | M-CMD-0010 M-CMD-0011 M-CMD-0012 M-CMD-0013 |
| | Paraffin Sections | PCR | GeneAmp PCR System 2700 or 2720 (Applied Biosystems) 3130xl Genetic Analyser (Applied Biosystems) | CE Based on standard method | M-CMD-0010 M-CMD-0011 M-CMD-0012 M-CMD-0013 |
| | Peripheral Blood | PCR | GeneAmp PCR System 2700 or 2720 (Applied Biosystems) | CE Based on standard method | M-CMD-0010 M-CMD-0011 |

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| | | | | 3130xl Genetic Analyser (Applied Biosystems) | | M-CMD-0012 M-CMD-0013 |
| Immunoglobulin gene somatic hypermutation Detection of genomic rearrangements associated with leukaemia and lymphoma | Bone Marrow | PCR | | GeneAmp PCR System 2700 or 2720 (Applied Biosystems) 3130xl Genetic Analyser (Applied Biosystems) | Non-CE Based on standard method | M-CMD-0038 |
| | Peripheral Blood | PCR | | GeneAmp PCR System 2700 or 2720 (Applied Biosystems) 3130xl Genetic Analyser (Applied Biosystems) | Non-CE Based on standard method | M-CMD-0038 |
| JAK2 V617F mutation Detection of mutations associated with myeloproliferative neoplasms | Bone Marrow | PCR | | GeneAmp PCR System 2700 or 2720 (Applied Biosystems) Dyad DNA Engine (Bio-Rad) | Non-CE Based on standard method | M-CMD-0032 M-CMD-0033 |
| | Peripheral Blood | PCR | | GeneAmp PCR System 2700 or 2720 (Applied Biosystems) Dyad DNA Engine (Bio-Rad) | Non-CE Based on standard method | M-CMD-0032 M-CMD-0033 |
| MYD88 L265P mutation test | PB/BM/FFPE/tissue | Multiplex PCR | | ABI 3130XL | Non-CE. Based on standard based methodology. Varettoni et al. Blood, 2013, Vol.121, no.13 p2522-2528. | M-CMD-0085, VP-CMD-0041 |
| NPM1 mutations Detection of mutations associated with leukaemia | Bone Marrow | PCR | | GeneAmp PCR System 2700 or 2720 (Applied Biosystems) 3130xl Genetic Analyser (Applied Biosystems) Dyad DNA Engine (Bio-Rad) | Non-CE Based on standard method | M-CMD-0041 M-CMD-0043 |
| | Peripheral Blood | PCR | | GeneAmp PCR System 2700 or 2720 (Applied Biosystems) 3130xl Genetic Analyser | Non-CE Based on standard method | M-CMD-0041 M-CMD-0043 |

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| | | | | (Applied Biosystems) Dyad DNA Engine (Bio-Rad) | | |
| PML-RARa fusion Detection of rearrangements associated with leukaemia | Bone Marrow | PCR | | GeneAmp PCR System 2700 or 2720 (Applied Biosystems) X2 Dyad DNA Engine (Bio-Rad) | Non-CE Based on standard method | M-CMD-0028 M-CMD-0039 |
| | Peripheral Blood | PCR | | GeneAmp PCR System 2700 or 2720 (Applied Biosystems) X2 Dyad DNA Engine (Bio-Rad) | Non-CE Based on standard method | M-CMD-0028 M-CMD-0039 |
| t (11; 14) Translocation Detection of genomic rearrangements associated with lymphoma | Bone Marrow | PCR | | Dyad DNA Engine (BioRad) GeneAmp PCR System 2700 or 2720 (Applied Biosystems) | CE Based on standard method | M-CMD-0016 M/CMD-0017 |
| | Fresh Biopsy | PCR | | Dyad DNA Engine (BioRad) GeneAmp PCR System 2700 or 2720 (Applied Biosystems) | CE Based on standard method | M-CMD-0016 M/CMD-0017 |
| | Paraffin Sections | PCR | | Dyad DNA Engine (BioRad) GeneAmp PCR System 2700 or 2720 (Applied Biosystems) | CE Based on standard method | M-CMD-0016 M/CMD-0017 |
| | Peripheral Blood | PCR | | Dyad DNA Engine (BioRad) GeneAmp PCR System 2700 or 2720 (Applied Biosystems) | CE Based on standard method | M-CMD-0016 M/CMD-0017 |
| T cell receptor gene rearrangements. Detection of genomic rearrangements associated with leukaemia and lymphoma. | Bone Marrow | PCR | | Hamilton Microlab STAR GeneAmp PCR System 2700/2720 (Applied Biosystems) 3130xl Genetic Analyser (Applied Biosystems) | CE Based on standard method | M-CMD-0010 M-CMD-0011 M-CMD-0012 M-CMD-0013 |

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|---|-------------------|-----|---|-----------------------------|--|
| | Fresh Biopsy | PCR | Hamilton Microlab STAR GeneAmp PCR System 2700 or 2720 (Applied Biosystems) 3130xl Genetic Analyser (Applied Biosystems) | CE Based on standard method | M-CMD-0010 M-CMD-0011 M-CMD-0012 M-CMD-0013 |
| | Paraffin Sections | PCR | Hamilton Microlab STAR GeneAmp PCR System 2700 or 2720 (Applied Biosystems) 3130xl Genetic Analyser (Applied Biosystems) | CE Based on standard method | M-CMD-0010 M-CMD-0011 M-CMD-0012 M-CMD-0013 |
| | Peripheral Blood | PCR | GeneAmp PCR System 2700 or 2720 (Applied Biosystems) 3130xl Genetic Analyser (Applied Biosystems) | CE Based on standard method | M-CMD-0010 M-CMD-0011 M-CMD-0012 M-CMD-0013 |
| t(14;18) translocation. Detection of genomic rearrangements associated with lymphoma. | Bone Marrow | PCR | Dyad DNA Engine (Bio-Rad) GeneAmp PCR System 2700 or 2720 (Applied Biosystems) | CE Based on standard method | M-CMD-0014 M-CMD-0015 |
| | Fresh Biopsy | PCR | Dyad DNA Engine (Bio-Rad) GeneAmp PCR System 2700 or 2720 (Applied Biosystems) | CE Based on standard method | M-CMD-0014 M-CMD-0015 |
| | Paraffin Sections | PCR | Dyad DNA Engine (Bio-Rad) GeneAmp PCR System 2700 or 2720 (Applied Biosystems) | CE Based on standard method | M-CMD-0014 M-CMD-0015 |
| | Peripheral Blood | PCR | Dyad DNA Engine (Bio-Rad) GeneAmp PCR System 2700 or 2720 (Applied Biosystems) | CE Based on standard method | M-CMD-0014 M-CMD-0015 |

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|--|---|-------------------|-------------------------------|---|---------------------------------------|--|
| | TP53 Mutational analysis | | PCR with NGS based sequencing | Ion Torrent S5, Ion Chef | Non-CE Based on standard method | M-CMD-0072 |
| 1033 Molecular pathology - .04 Chimersim studies | Chimerism, Post Allogeneic Stem Cell Transplant Monitoring | Bone Marrow | PCR | Veriti (Applied Biosystems) Dyad DNA Engine (BioRad) 3130xl Genetic Analyser (Applied Biosystems) | Non-CE Based on standard method | M-CMD-0018 M-CMD-0019 M-CMD-0020 M-CMD-0021 |
| | | Peripheral Blood | PCR | Veriti (Applied Biosystems) Dyad DNA Engine (BioRad) 3130xl Genetic Analyser (Applied Biosystems) | Non-CE Based on standard method | M-CMD-0018 M-CMD-0019 M-CMD-0020 M-CMD-0021 |
| | Provenance Testing | Bone Marrow | PCR | Veriti (Applied Biosystems) Dyad DNA Engine (BioRad) 3130xl Genetic Analyser (Applied Biosystems) | Non-CE Based on standard method | M-CMD-0018 M-CMD-0019 M-CMD-0020 M-CMD-0021 M-CMD-0048 |
| | | Paraffin Sections | PCR | Veriti (Applied Biosystems) Dyad DNA Engine (BioRad) 3130xl Genetic Analyser (Applied Biosystems) | Non-CE Based on standard method | M-CMD-0018 M-CMD-0019 M-CMD-0020 M-CMD-0021 M-CMD-0048 |
| | | Peripheral Blood | PCR | Veriti (Applied Biosystems) Dyad DNA Engine (BioRad) 3130xl Genetic Analyser (Applied Biosystems) | Non-CE Based on standard method | M-CMD-0018 M-CMD-0019 M-CMD-0020 M-CMD-0021 M-CMD-0048 |
| | T Cell Chimerism Post Allogenic Stem Cell Transplant Monitoring | | PCR | Veriti (Applied Biosystems) Dyad DNA Engine (BioRad) 3130xl Genetic Analyser (Applied Biosystems) | Non-CE Based on standard method | M-CMD-0006 |

The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratory's approved and documented procedures.

Note 1 - Range may be extended for the test

Note 2 – New parameters/tests may be added

Note 3 – New matrices may be added

Note 4 – Changes to equipment/kits where the underlying methodology does not change

For further details please refer to the laboratory's 'List of flexible scope changes', available directly from the laboratory.

Histopathology and Cytopathology

Category: A

| Medical pathology field - Test | Test/assay | Specimen Type | Equipment/Technique | Method (CE/Non-CE/In house developed/based on standard method) | Range of measurement | Std. ref & SOP |
|--|---|------------------------|--|--|----------------------|--|
| 1055 Molecular pathology - .01 Assay for somatic variants in DNA sequence(s) | Analysis of solid tumours using Cancer Hotspot mutation panel. Colorectal cancer panel, Lung Adenocarcinoma Panel, GIST Panel and Melanoma Panel. | FFPE tissue | Ion Torrent S5 Sequencer, Ion Chef, 7500 real Time PCR System, Hamilton Star Automated Library preparation system | Non-CE, based on standard method | NA | M-CMD-0058, M-CMD-0071, M-CMD-0073, M-CMD-0074, M-CMD-0078 |
| | Detection of deletions or duplications in the BRCA1 and BRCA2 genes by Multiplex Ligation-Dependent Probe Amplification | Peripheral Blood | Bio-rad Thermal cycler Pre-PCR; SimpliAmp Thermal Cyclers Post PCR; QiaSymphony DNA Extraction; 3500xl; MLPA fragment analysis | Non-CE, based on standard method | NA | M-CMD-0084, M-CMD-0088, F-CMD-0154 |
| | Detection of EGFR mutations in cfDNA using NGS technology | | MagNAPure 24 (Roche), Hamilton Star Automated Library preparation system, Ion Torrent S5 Sequencer | Non-CE, based on standard method | NA | M-CMD-0079 M-CMD-0080 |
| | Detection of tBRCA pathogenic mutations using smMIP Panels | Peripheral Blood, FFPE | SimpliAmp Thermal Cyclers, QiaSymphony DNA Extraction, Illumina NextSeq / Capture based smMIP sequencing | Laboratory developed test | NA | M-CMD-0076, M-CMD-0077 |

Category: A

| Medical pathology field - Test | Test/Assay | Specimen Type | Equipment/Technique | Method (CE/Non-CE/In house developed/based on standard method) | Range of measurement | Std. Ref & SOP |
|---|---|---------------|---|--|---|----------------|
| 1040 Immunology - .01 Quantitative investigation of immunoglobulins G,A,M and D in body fluids | Detection of Oligclonal IgG in CSF **1,2,3,4 | CSF | Roche COBAS 6000 system | CE Marked | CSG IgG: 4 - 200 mg/L | LM-IMM-0051 |
| | Detection of Oligclonal IgG in Serum **1,2,3,4 | Serum | Roche COBAS 6000 system | CE Marked | IgG: 0.3-50.0 g/L | LM-IMM-0051 |
| | Detection of Oligoclonal IgG in CSF **1,2,3,4 | CSF | Sebia Hydrasis / Isoelectric Focussing | CE Marked | N/A | LM-IMM-0060 |
| | IgG1 **1,2,3,4 | Serum | Turbimetry /Optilite | CE Method | 0.15-144g/L | LM-IMM-0075 |
| | IgG2 **1,2,3,4 | | Turbimetry / Optilite | CE Method | 0.02-28 g/L | LM-IMM-0075 |
| | IgG3 **1,2,3,4 | | Turbimetry / Optilite | CE Method | 0.05-8.8g/L | LM-IMM-0075 |
| | IgG4 **1,2,3,4 | | Turbimetry / Optilite | CE Method | 0.0043-64.8g/L | LM-IMM-0075 |
| | Investigation of Monoclonal Gammopathies in Serum **1,2,3,4 | | Roche COBAS 6000 system | CE Marked | IgG: 0.3-50.0 g/L IgA: 0.05-8.0 g/L IgM: 0.25 - 6.5 g/L | LM-IMM-0051 |
| | Investigation of Monoclonal Gammopathies in Serum **2,3,4 | | Sebia Cappillarys 3 / Electrophoresis | CE Marked | N/A | LM-IMM-0064 |
| | | | Sebia Hydrasis / Immunophenotyping / Immunofixation | CE Marked | N/A | LM-IMM-0064 |

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| | Investigation of Monoclonal Gammopathies in Urine | Urine | Roche COBAS 6000 | CE Marked | N/A - Identification by Immunofixation | LM-IMM-0051 |
| | Investigation of Monoclonal Gammopathies in Urine **1,2,3,4 | | Sebia Hydrasis / Electrophoresis | CE Marked | N/A | LM-IMM-0007 |
| | | | Sebia Hydrasis / Immunofixation | CE Marked | N/A | LM-IMM-0007 |
| 1040 Immunology - .03 Total IgE | Quantitative investigation of Total IgE in Serum **1,2,3,4 | Serum | Phadia 2500 Enzyme Immunoassay | CE Marked | Total IgE: 2.0 - 5000 IU/mL | LM-IMM-0036 |
| 1040 Immunology - .04 Allergen - specific IgE | ALEX2 Allergy testing **1,2,3,4 | | Manual method, Alex Raptor analysis software | CE Method | Specific IgE 0.3-50 KUA/L, Total IgE 20-2500 | LM-IMM-0076 |
| | Quantitative investigation of Serum samples for Allergen specific IgE & specific IgG **1,2,3,4 | | Enzyme Immunoassay / Phadia 250 | CE Marked | Specific IgE: 0 - 100 IU/L Specific IgG: 02-200 mg/L | LM-IMM-0035 |
| | Quantitative investigation of Serum samples for Allergen specific IgE **1,2,3,4 | | Phadia 2500 Enzyme Immunoassay | CE Marked | Specific IgE: 0.1 - 100 KU/L | LM-IMM-0036 |
| 1040 Immunology - .06 Investigation of complement | C1 inhibitor **1,2,3,4 | | Turbimetry / Optilite | CE Method | 0.08-0.88 g/L | LM-IMM-0075 |
| | Evaluation of Alternative Haemolytic Complement Activity **2,3,4 | | Dynex DS2 /ELISA | CE Marked | Functional Assay | LM-IMM-0063 |
| | Evaluation of Classical Haemolytic Complement Activity **2,3,4 | | Dynex DS2 / ELISA | CE Marked | Functional Assay | LM-IMM-0063 |
| | Quantitative Investigation of C3 Complement component **1,2,3,4 | | Roche Cobas system/Turbimetry | CE marked | 0.04-5.0g/L | LM-IMM-0051 |

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|---|--|-------|--|-----------|-----------------------------|--------------|
| | Quantitative Investigation of C4 Complement Components **1,2,3,4 | | Roche COBAS System/Turbidimetry | CE Marked | C4:0.02-1.0g/L | LM-IMM-0051 |
| 1040 Immunology - .08 Detection of immune complexes in body fluids and biopsy material | Quantitative Determination of β -amyloid (1-42) **1,2,3,4 | CSF | Dynex DS2 Analyser/Enzyme Immunoassay | CE Marked | 5 - 2000pg/ml | LM-IMM-0057 |
| | Quantitative Determination of Phospho Tau (181P) **1,2,3,4 | | Dynex DS2 Analyser / Enzyme Immunoassay | CE Marked | 125 - 2000 pg/ml | LM-IMM-0057 |
| | Quantitative Determination of Total Tau (hTau Ag) **1,2,3,4 | | Dynex DS2 Analyser / Enzyme Immunoassay | CE Marked | 75 - 1200 pg/ml | LM-IMM-0057 |
| 1040 Immunology - .10 Rheumatoid factor - quantitative assays | Rheumatoid Factor **1,2,3,4 | Serum | Roche COBAS 6000 System/Turbidimetry | CE Marked | RF: 10-130 IU/ml | LM-IMM-0051 |
| 1040 Immunology - .12 Detection of autoantibodies in body fluids and biopsy material | Cardiolipin IgG **1,2,3,4 | | Phadia Immunocap 250/Enzyme Immunoassay | CE Marked | IgG Card: 0.5 - 418 GLPU/ml | LM-IMM-0052 |
| | | | Phadia Immunocap 2500/Enzyme Immunoassay | CE Marked | IgG Card: 0.5 - 418 GLPU/ml | LM-IMM-0052 |
| | CCP **1,2,3,4 | | Phadia Immunocap 250/Enzyme Immunoassay | CE Marked | CCP: 0.4 - 340 U/ml | LM-IMM-0052, |
| | | | Phadia Immunocap 2500/Enzyme Immunoassay | CE Marked | CCP: 0.4 - 340 U/ml | LM-IMM-0052 |
| | Centromere Screen **1,2,3,4 | | Phadia 250 / Enzyme Immunoassay | CE Marked | 0.4 - 240 U/ml | LM-IMM-0052 |
| | | | Phadia 2500 / Enzyme Immunoassay | CE Marked | 0.4 - 240 U/ml | LM-IMM-0052 |
| | CTD Screen **1,2,3,4 | | Phadia 250 / Enzyme Immunoassay | CE Marked | 0.03 - 32 Ratio | LM-IMM-0052 |
| | | | Phadia 2500/Enzyme Immunoassay | CE Marked | 0.03 - 32 Ratio | LM-IMM-0052 |

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|--|--|-----------|---|----------------------------|
| Detection of Autoimmune Liver Diseases (IgG) by Immunoblot **2,3,4 | Test Kit/Immunoblot | CE Marked | Qualitative Method: No measurement range provided | LM-IMM-0068 |
| dsDNA **1,2,3,4 | Phadia Immunocap 250/Enzyme Immunoassay | CE Marked | dsDNA: 0.5-379 IU/ml | LM-IMM-0052 |
| ENA Profile (RNP, Sm, Ro, LA, Scl-70, Jo01) **1,2,3,4 | Phadia Immunocap 2500/Enzyme Immunoassay | CE Marked | dsDNA: 0.5-379 IU/ml | LM-IMM-0052 |
| | Phadia Immunocap 250/Enzyme Immunoassay | CE Marked | RNP:0.3 - 240 ELIA U/ml SM:0.1-120 ELIA U/ml Ro: 0.3-240 ELIA U/ml La: 0.3-320 ELIA U/ml Scl70:0.4-240 ELIA U/ml Jo1:0.3-240 ELIA U/ml | LM-IMM-0052 |
| | Phadia Immunocap 2500/Enzyme Immunoassay | CE Marked | RNP:0.3 - 240 ELIA U/ml SM:0.1-120 ELIA U/ml Ro: 0.3-240 ELIA U/ml La: 0.3-320 ELIA U/ml Scl70:0.4-240 ELIA U/ml Jo1:0.3-240 ELIA U/ml | LM-IMM-0052 |
| ENA Profile (Ro, La, RNP, SMDP-S, Jo-1, Scl-70) | Phadia 2500/Enzyme Immunoassay | CE marked | Ro: 0.3-240U/ml, La: 0.5-416U/ml, RNP: 0.3-240U/ml, SMDP-S: 0.7-330U/ml, Jo-1: 0.3-240U/ml, Scl-70: 0.3-240U/ml | LM-IMM-0052 LP-IMM-0097 |
| GAD **1,2,3,4 | ELISA Enzyme Immunassay / Dynex DS2 | CE Marked | GAD: 5 - 2000 IU/ml | LM-IMM-0047 |
| GBM **1,2,3,4 | Phadia Immunocap 250/Enzyme Immunoassay | CE Marked | GBM: 0.8-680 IU/ml | LM-IMM-0052 |
| | Phadia Immunocap 2500/Enzyme Immunoassay | CE Marked | GBM: 0.8-680 IU/ml | LM-IMM-0052 |
| Myeloperoxidase **1,2,3,4 | Phadia Immunocap 250/Enzyme Immunoassay | CE Marked | MPO: 0.2 - 134 IU/ml | LM-IMM-0052 |

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|---|---|------------------|---|-----------|--|----------------------------|
| | | | Phadia Immunocap 2500/Enzyme Immunoassay | CE Marked | MPO: 0.2 - 134 IU/ml | LM-IMM-0052 |
| | Myositis Specific Antibodies **2,3,4 | | Test Kit/Immunoblot | CE Marked | Myositis Immunoblot: 0-50 Signal Intensity | LM-IMM-0062 |
| | Neuronal (Paraneoplastic) Immunofluorescence & immunoblot **2,3,4 | | Test Kit/Indirect Immunofluorescence/Immunoblot | CE Marked | Qualitative method (presence or absence of autoantibodies) /Signal Intensity | LM-IMM-0066 LM-IMM-0067 |
| | Proteinase-3 **1,2,3,4 | | Phadia Immunocap 250/Enzyme Immunoassay | CE Marked | PR3: 0.2 - 177 IU/ml | LM-IMM-0052 |
| | Thyroid Peroxidase (TPO) **1,2,3,4 | | Phadia Immunocap 2500/Enzyme Immunoassay | CE Marked | PR3: 0.2 - 194 IU/ml | LM-IMM-0052 |
| | tTg (IgA) **1,2,3,4 | | Phadia Immunocap 250 / Enzyme Immunoassay | CE Marked | TPO: 4-1542 IU/ml | LM-IMM-0052 |
| | β2 Glycoprotein **1,2,3,4 | | Phadia Immunocap 2500/Enzyme Immunoassay | CE Marked | TPO: 4-1542 IU/ml | LM-IMM-0052 |
| | | | Phadia Immunocap 250/Enzyme Immunoassay | CE Marked | tTG: 0.1 - 128 U/ml | LM-IMM-0052 |
| | | | Phadia Immunocap 2500/Enzyme Immunoassay | CE Marked | tTG: 0.1 - 128 U/ml | LM-IMM-0052 |
| | | | Phadia Immunocap 250/Enzyme Immunoassay | CE Marked | β2: 0.6-532 IU/ml | LM-IMM-0052 |
| | | | Phadia Immunocap 2500/Enzyme Immunoassay | CE Marked | β2: 0.6-532 IU/ml | LM-IMM-0052 |
| 1040 Immunology - .13 Cryoglobulins | Identification of the Presence of Cryoglobulins **2,3,4 | | Sebia Hydrasis/Immunofixation | CE Marked | Presence detected visually | LM-IMM-0013 |
| 1040 Immunology - .14 β2-microglobulin | Quantitative Determination of β-2 Microglobulin **1,2,3,4 | | Roche COBAS 6000 System/Turbidimetry | CE Marked | B2M: 0.1 - 8.0 mg/L | LM-IMM-0051 |
| 1040 Immunology - .23 Tests of cellular immunity - quantitation of lymphocytes | Enumeration of Lymphocyte Subsets **1,2,4 | EDTA Whole Blood | Becon Dickinson FacsCanto/Flow Cytometry | CE Marked | Enumeration using Becton Dickenson FacsCanto | LM-IMM-0045 |

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|--|--|-------|---|--------------------------|--|-------------|
| | Measurement of Activation Markers (HLA-DR, CD25, CD38) on CD4 & CD8 T cells **1,2,4 | | Becton Dickinson/Flow Cytometry | Based on Standard Method | Enumeration using Becton Dickenson FacsCanto | LM-IMM-0055 |
| | Measurement of Double-Negative T Cell receptor alpha beta and gamma delta T cells **1,2,4 | | Becton Dickinson/Flow Cytometry | Based on Standard Method | Enumeration using Becton Dickenson FacsCanto | LM-IMM-0055 |
| | Measurement of Naïve, Memory and Class Switch Memory B Cell Subsets **1,2,4 | | Becton Dickinson/Flow Cytometry | Based on Standard Method | Enumeration using Becton Dickenson FacsCanto | LM-IMM-0055 |
| | Measurement of Naïve, Memory and Effector T Cell Subsets **1,2,4 | | Becton Dickinson/Flow Cytometry | Based on Standard Method | Enumeration using Becton Dickenson FacsCanto | LM-IMM-0055 |
| 1040 Immunology - .30 Assessment of neutrophils and monocytes - quantitation | Measurement of Adhesion Molecules CD18, CD11a, CD11b, CD11c on Neutrophils **1,2,4 | | Becton Dickinson/Flow Cytometry | Based on Standard Method | Enumeration using Becton Dickenson FacsCanto | LM-IMM-0040 |
| 1040 Immunology - .32 Assessment of neutrophils and monocytes - in vitro functional tests | Functional Analysis of Neutrophils **2,3,4 | | Becton Dickinson FacsCanto/Flow Cytometry | Based on standard method | N/A Functional Assay | LM-IMM-0029 |
| 1040 Immunology - .36 Cell markers | Assessment of T-cell proliferation to mitogenic and physiological-like stimulation **2,3,4 | | Becton Dickinson FacsCanto/Flow Cytometry | Based on standard method | Enumeration using Becton Dickenson FacsCanto | LM-IMM-0070 |
| 1040 Immunology - .41 HLA - B27 | HLA B27 phenotype **2,3,4 | | Becton Dickinson/Flow Cytometry | CE Marked | Enumeration using Becton Dickenson FacsCanto | LM-IMM-0069 |
| 1040 Immunology - .54 Tryptase | Tryptase **1,2,3,4 | Serum | Phadia Immunocap 250/Enzyme Immunoassay | CE Marked | TRYP: 1.0 - 200 µg/L | LM-IMM-0037 |

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|--|---|-------------|--|-------------------------------|---|--------------------------------|
| 1040 Immunology - .60 Simple slide tests for biochemical and immunological analytes | ANA Autoantibodies **1,2,3,4 | | INOVA QUANTA-Lyser 240/Indirect Immunofluorescence | CE Marked | 1/80 - 1/160 | LM-IMM-0039 |
| | ANCA Autoantibodies **1,2,3,4 | | INOVA QUANTA-Lyser 240/Indirect Immunofluorescence | CE Marked | 1/20. | LM-IMM-0004 |
| | Anti-neutrophil cytoplasmic antibodies (ANCA) **2,3,4 | | Helios HTC/Indirect Immunofluorescence | CE marked | Qualitative | LM-IMM- 0004 LP-IMM-0104 |
| | Anti-nuclear antibodies (ANA) **2,3,4 | | Helios HTC/Indirect Immunofluorescence | CE marked | Negative or 1/80- 1/160 | LM-IMM- 0039 LP-IMM-0104 |
| | BP Autoantibodies **1,2,3,4 | | Indirect Immunofluorescence | CE Marked | 1/10 - 1/80 | LM-IMM-0020 |
| | dsDNA antibodies **1,2,3,4 | | Helios HTC/Indirect Immunofluorescence | CE marked | Negative or 1/20- 1/160 | LM-IMM- 0014 LP-IMM-0104 |
| | Encephalitis Mosaic for detection of NMDA, LGI-1, CASPR2, AMPA 1/2, GABAB and DPPX **2,3,4 | Serum / CSF | Test Kit/Indirect Immunofluorescence/Immunoblot | CE Marked | Qualitative method (presence or absence of autoantibodies) | LM-IMM-0071 |
| | IgA Endomysial antibodies (EMA) *2,3,4 | Serum | Helios HTC/Indirect Immunofluorescence | CE marked | Qualitative | LM-IMM- 0017 LP-IMM-0104 |
| | IgG Endomysial antibodies (EMA) *2,3,4 | | Helios HTC/Indirect Immunofluorescence | CE marked | Qualitative | LM-IMM- 0017 LP-IMM-0104 |
| | LKS Screen **1,2,3,4 | | INOVA QUANTA-Lyser 240/Indirect Immunofluorescence | CE Marked | 1/40 - 1/160 | LM-IMM-0005 |
| LKS screen *1,2,3,4 | Helios HTC/Indirect Immunofluorescence | | CE marked | Qualitative or 1/40- 1/160 | LM-IMM- 0005 LP-IMM-0104 | |
| PV Autoantibodies **1,2,3,4 | Indirect Immunofluorescence | | CE Marked | 1/10 - 1/80 | LM-IMM-0053 | |

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|---|--|-------------|---------------------------------------|------------------------------------|---|------------------------------|
| 1040 Immunology - .61 Proteins, quantitative analysis | Albumin **1,2,3,4 | CSF | Roche COBAS System/Turbidimetry | CE Marked | CSF Albumin: 36- 4800 mg/L | LM-IMM-0051, LM- IMM-0060 |
| | | Serum | Roche COBAS System/Turbidimetry | CE Marked | Serum Albumin: 3- 101 g/L | LM-IMM-0051, LM- IMM-0060 |
| | Alpha-1 Antitrypsin (AAT) **1,2,3,4 | | Roche COBAS System/Turbidimetry | CE Marked | AAT: 0.2-6.0 g/L | LM-IMM-0051 |
| | Caeruloplasmin **1,2,3,4 | | Roche COBAS System/Turbidimetry | CE Marked | 0.03-1.4 g/L | LM-IMM-0051 |
| | CD163 **1,2,3,4 | Urine | ELISA | CE marked | 0-13.61ng/ml | LM-IMM-0059 |
| | CD25/IL-2 Ra **1,2,3,4 | Serum | ELISA/Dynex DS2 | Based on standard method | 0-5000pg/mL | LM-IMM-0074 |
| | Cytokine Profile IL-1b **1,2,3,4 | | Immunoassay/Protein Simple Ella | Based on standard method | 0.16-1530pg/mL | LM-IMM-0077 |
| | Cytokine Profile IL-6 **1,2,3,4 | | Immunoassay/Protein Simple Ella | Based on standard method | 0.28-2652 pg/mL | LM-IMM-0077 |
| | Cytokine Profile IL- 8/CXCL8 **1,2,3,4 | | Immunoassay/Protein Simple Ella | Based on standard method | 0.19-1804pg/mL | LM-IMM-0077 |
| | Cytokine Profile - TNFa **1,2,3,4 | | Immunoassay/Protein Simple Ella | Based on standard method | 0.3-1160pg/mL | LM-IMM-0077 |
| | Free Kappa/Free Lambda **1,2,3,4 | | Turbimetry / Optilite | CE Method | Kappa 0.6 - 127000 mg/L Lambda 1.3-139000 mg/L | LM-IMM-0075 |
| | IL-6 **1,2,3,4 | | Dynex DS2 / ELISA | Based on standard method | 0-300pg/mL | LM-IMM-0073 |
| | Total Protein **1,2,3,4 | | Roche COBAS System/Turbidimetry | CE Marked | Total Protein: 2- 120g/L | LM-IMM-0051, LM- IMM-0064 |
| | | | Urine | Roche COBAS System/Turbidimetry | CE Marked | Total Protein:0.040- 2g/L |
| Transferrin **1,2,3,4 | Serum | | Roche COBAS System/Turbidimetry | CE Marked | Transferrin: 0.1-5.2 g/L | LM-IMM-0051 |
| 1040 Immunology - .99 Miscellaneous tests | Detection of Immunoglobulins and Complement by Direct Immunofluorescence **2,4 | Skin Biopsy | Cryostat/Direct Immunofluorescence | Based on Standard Method | Presence of Antibodies detected by Direct Immunofixation | LM-IMM-0042 |

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|--|---|-------|--------------------------|--------------------------|-------------------------|----------------------------|
| | Haemophilus Influenza Type B **1,2,3,4 | Serum | ELISA/ Dynex DS2 | CE Marked | HIB: 0.11 - 9.0 U/ml | LM-IMM-0023 |
| | Interferon Gamma Release Assay **1.2.3.4 | | ELISA/ Dynex DS2 | CE Marked | IGRA: 0.05 - 10.0 IU/ml | LM-IMM-0061 |
| | Investigation and Identification of Urinary Casts **2,4 | Urine | Microscope/Manual Method | Based on Standard Method | N/A | LM-IMM-0038 |
| | Phospholipase A2 Receptor Antibody **1,2,3,4 | Serum | ELISA / Dynex DS2 | CE Marked | 2 - 1500 RU/ml | LP-IMM-0092 LM-IMM-0078 |
| | Pneumococcus Total IgG antibodies **1,2,3,4 | | Dynex DS2/ELISA | CE Marked | PCP IgG: 3.3 - 270 U/ml | LM-IMM-0025 |
| | Tetanus antibodies **1,2,3,4 | | ELISA/ Dynex DS 2 | CE Marked | TET: 0.01 - 7 U/ml | LM-IMM-0025 |

The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratory's approved and documented procedures.

Note 1 - Range may be extended for the test

Note 2 – New parameters/tests may be added

Note 3 – New matrices may be added

Note 4 – Changes to equipment/kits where the underlying methodology does not change

For further details please refer to the laboratory's 'List of flexible scope changes', available directly from the laboratory.

Head Office

Microbiology and Virology

Category: A

| Medical pathology field - Test | Test/assay | Specimen Type | Equipment/Technique | Method (CE/Non-CE/In house developed/based on standard method) | Range of measurement | Std. ref & SOP |
|--|--|--|---------------------|--|----------------------|-------------------------------|
| 1011 Macroscopic examination and description | Macroscopic Examination and Description **,3 | Artificial Devices, Aspirates, BAL, BAL Washings, Bile, Biopsies, Blood Transfusion Products, Blood, Fluids, Bone Marrow, bronchial Brushings, Cerebrospinal Fluid, Cervical Swabs, Corneal Scrapings, contact lenses, Cryobiology Products, Dermal Swabs, Duodenal/Jejunal Aspirates, Ear Swabs, Endocervical Swabs, Eye Swabs, Faeces, Gastric Washings, Fluids, penile swab, Hair, High Vaginal Swabs, Liver Aspirate, Male Urethral Swabs, Mouth Swabs, Nail, Nasal Swabs, Ocular Swabs, Perianal Swabs, Penile swabs, Pharyngeal Swabs, | Manual | Based on Standard Method | N/A | LP-MICRO-0001 LP-IMRL-0001 |

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| | | Pus, Rectal Swabs, Respiratory Specimens, Skin Swabs, Sputum, Throat Swabs, Tips, Tissues, Urethral Swabs, Urine, Vulval swab Wound Swabs, worm | | | | |
| | Manual determination of Leucocytes and Blood in urine using Combur 7 Test **1,4 | Urine | Manual/ Urine Strip test | CE Marked | Semi Quantitative: Leucocytes: Negative, +: 10-25 Leu/μl, ++: 75Leu/μl, +++ 500Leu/μl , Blood: Negative, +: 5- 10 ERY/μl, ++: 25 ERY/μl, +++:50 ERY/μl, ++++ :250 ERY/μl | LM-MICRO-0019 |
| 1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .01 Microscopic examination for general bacteriology purposes (including enumeration and description of human cells) | Preparation of Films on Glass Slides for General Bacteriology Purposes-Gram Stain **3,4 | Artificial Devices, BAL, BAL Washings, Biopsies, , Blood, Fluids, Bone Marrow, bronchial Brushings, Cerebrospinal Fluid, Cervical Swabs, Aspirates, , Endocervical Swabs, Eye Swabs , Fluids, High Vaginal Swabs, Mouth Swabs,Pus, Respiratory Specimens, Sputum, Tissues, Urethral Swabs, Urine, Wound Swabs, Rectal Swabs | Microscope/Manual | CE Marked | Positive / Negative | LM-MICRO-0001,04, 06, 07, 08, 09, 10, 11, 13, 14, 15, 16, 19, 20, 23, 24, 25, 26, 27, 28, 29, 30, 32, 33, 37, 43, 48, 52 |
| | Red Cell Count, White Cell Count & White Cell Differential Stain **1,3,4 | Cerebrospinal Fluid | Microscope/Manual | Based on Standard Method | Red Cells, White Cells per uL. Differential: % PMNs, % Monocytes | LM-MICRO-0020, 35 |

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| | Urine Microscopy **1,3,4 | Urine | Microscope/Manual | Based on Standard Method | WCC,RCC <10, 10-100, >100 per ul. | LM-MICRO-0019 |
| | Urine Microscopy automated **1,3,4 | Urine: Mid Stream Urine, Catheter specimen Urine. | UF5000/ Flow cytometry for automated urine microscopy | CE Marked | WCC,RCC <20 to >1000 per ul. | LM-MICRO-0019,LP- MICRO-0220 |
| 1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .03 Microscopic examination for fungi | Microscopic Examination for Fungi including Calcofluor White Stain **2,3,4 | Skin scrapings, Hair, Nail, Biopsies, Tissues, Aspirates | Microscope/Manual | CE Marked | Positive / Negative | LM-MICRO-0022, 34, 41 |
| 1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .04 Microscopic examination for mycobacteria | Automated GRAM and Ziehl-Neelsen (ZN) dual staining **2,3,4 | Microscope slides smearred with culture material. | Dagatron Dual stainer (GRAM and ZN) instrument (AT-3002) /Gram stain/ ZN Stain. | CE Marked | Gram Positive/ Negative / ZN positive/ Negative | LM-IMRL-0008 |
| | Microscopic examination of Mycobacterial isolates by the Ziehl- Neelsen Stain **2,3,4 | Positive Mycobacterial Cultures, | Manual/Microscope | Based on Standard Method | Positive / Negative | LM-IMRL-0002, 08 |
| | Microscopic screening of specimens for Mycobacteria using Auramine Stain **2,3,4 | Respiratory samples, tissues, biopsies , Gastric washings, Early morning Urine, CSF, Body Fluids, Skin & tissues specimens, Abscess, Pus, Wound swab, Blood Culture, Bone Marrow, EBUS | Microscope/Manual | Based on Standard Method | Positive / Negative | LM-IMRL-0001, 08 |
| 1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring | Automated Culture of Specimens for General Bacteria **2,3,4 | Cervical Swabs, Dermal Swabs, Ear Swabs, Endocervical Swabs, Eye Swabs, , Genital Swabs, High | WASP Walk away specimen processor. | CE Marked | Growth / no growth. | LM-MICRO-0002, LP- MICRO-0214 |

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| for growth - .01 Culture of general bacteria | | Vaginal Swabs, Mouth Swabs, Nasal Swabs, , Perianal Swabs, Pharyngeal Swabs, Pus swab, Rectal Swabs, Skin Swabs, Throat Swabs, Urethral Swabs, Urine, Vulval Swabs, Wound Swabs, Groin Swabs | | | | |
| | Culture of screening swabs for CPE **2,3,4 | Rectal Swabs and Faeces | Manual Inoculation on CPE Chromogenic agar | CE Marked | Growth/No Growth | LM-MICRO-0057 |
| | Culture of screening swabs for MRSA **2,3,4 | Nasal, Throat, Groin swabs | Manual Inoculation on MRSA chromogenic agar | CE Marked | Growth / No growth | LM-MICRO-0014 |
| | Culture of screening swabs for VRE **2,3,4 | Faeces, Rectal Swabs, Colonic Aspirates | Manual/ inoculation on VRE chromogenic agar | CE Marked | growth / no growth | LM-MICRO-0057 |
| | Culture of Specimens for General Bacteria **2,3,4 | Artificial Devices, BAL, BAL Washings, Bronchial Brushings, Bile, Biopsies, Blood Transfusion Products, Fluids, Bone Marrow, Cerebrospinal Fluid, Cervical Swabs, Colonic Aspirates, Corneal Scrapings, CRE Screening swabs, Cryobiology Products, Dermal Swabs, Aspirates, Ear Swabs, Endocervical Swabs, Eye Swabs, Faeces, Fluids, Genital Swabs, Hair, High Vaginal Swabs, Mouth Swabs, Nasal | Manual | CE Marked | growth / no growth | LM-MICRO-0002, 04, 06, 07, 08, 09, 10, 11, 13, 14, 15, 16, 19, 20, 23, 24, 25, 26, 27, 28, 29, 32, 33, 37, 43, 48, 55 |

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| | | Swabs, Perianal Swabs, Pharyngeal Swabs, Pus, Rectal Swabs, Respiratory Specimens, Skin Swabs, Spleen Aspirate, Sputum, Throat Swabs, Tips, Tissues, Urethral Swabs, Urine, Vulval Swabs, Wound Swabs | | | | |
| | Detection of organisms (other Than Mycobacterium Species) from Blood Cultures *3,4 | Blood/Fluids | Bact/Alert Virtuo Blood culture microbial detection system/colorimetric detection of CO2 | CE Marked | Detected/Not Detected | LM-MICRO-0030, LP-MICRO-0229 |
| 1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .02 Culture of fungi | Culture of specimens for superficial and systemic mycoses **2,3,4 | Skin, Hair, Nail, Biopsies, Tissues, any sample specifically requesting prolonged fungal culture | Manual | CE marked | Growth / no growth | LM-MICRO-0022, 41 |
| 1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .03 Culture of mycobacteria | Culture of isolates for Mycobacteria **3,4 | bacterial isolates | Becton Dickinson Bactec MGIT 960 | CE Marked | growth / no growth | LM-IMRL-0001, 02 |
| | Culture of specimens for Mycobacteria **3,4 | Sputum, Induced sputum, BAL, Bronchial Washings, Bronchial Brushings, Biopsies, Gastric Washings, Early Morning Urine, Cerebrospinal Fluid, Pleural Fluids, Peritoneal Fluids, Synovial Fluids, Pericardial Fluids, Skin, Tissue, | Becton Dickinson Bactec MGIT 960 / Manual Lowenstein Jenson Slopes | CE Marked | Growth / no growth | LM-IMRL-0001, 02 |

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| | | Abscess Contents, Aspirated Pus, Wound Swabs, Blood, Bone Marrow, EBUS | | | | |
| | Detection of mycobacterium species **3,4 | Blood | Becton Dickinson Bactec FX40 instrument | CE Marked | Growth / No growth | LM-IMRL-0001,LM-IMRL-0002 |
| 1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .01 Slide agglutination, | Salmonella , Shigella & Vibrio serology **3,4 | Bacterial isolates | Manual / Slide agglutination | CE marked | Positive / Negative | LM-MICRO-0029 |
| 1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .02 Particle agglutination | Detection of antibodies to Treponema pallidum **1,3,4 | Serum | Manual/ Particle agglutination | CE Marked | Qualitative: Negative or Positive & Semiquantitative: 1:80 to titre of >2560 | LM-SERO-0008 |
| | Immulex S. Pneumonia Omni **3,4 | Bacterial Isolate | Manual/Immulex S. pneumonia Omni | CE Marked | Positive / Negative | LM-MICRO-0036 |
| | Non-Treponemal test for the qualitative and semi quantitative detection of Syphilis-RPR **1,3,4 | Serum | Manual/ Particle Agglutination | CE Marked | Qualitative: Negative or Positive & Semiquantitative: Neat to titre of >1024 | LM-SERO-0007 |
| | Pastorex Staph Plus Test **3,4 | Bacterial Isolate | Manual/Particle agglutination | CE Marked | Positive / Negative | LM-MICRO-0036,LM-MRSA-0002 |
| | Potassium Hydroxide (String) Test **3,4 | | Manual | Based on Standard Method | Positive / Negative | LM-MICRO-0036 |
| | Streptococcal Grouping **3,4 | | Manual/Particle agglutination | CE Marked | Qualitative agglutination or non-agglutination. | LM-MICRO-0036 |
| 1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - | Detection of Aspergillus Galactomannan Antigen **3,4 | Blood, BAL | Manual/EIA | CE Marked | Qualitative: Negative/Positive | LM-SERO-0016 |

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| .03 Enzyme immunoassay, | | | | | | |
| | Detection of C. difficile toxin **3,4 | Faecal specimens | Manual/ Rapid Membrane Enzyme Immunoassay /Membrane Enzyme Immunoassay for the Simultaneous Detection of Clostridium difficile Glutamate Dehydrogenase Antigen and Toxins A and B in Faecal Specimens | CE Marked | Positive / Negative. | LM-MICRO-0029 |
| 1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04 Immuno chromatographic methods, | Detection of Cryptococcal antigen **1,3,4 | CSF, Serum | Manual/lateral flow assay | CE Marked | Qualitative Positive/Negative , semi quantitative neat to 2560 | LM-MICRO-0052 |
| | Detection of Legionella pneumophila and Streptococcus pneumoniae urinary antigen **3,4 | Urine | Manual / lateral flow assay | CE Marked | Qualitative Positive/ Negative | LM-MICRO-0055 |
| | Geenius HIV 1/2 Confirmatory Assay for the confirmation and differentiation of individual antibodies to HIV-1 and HIV-2 | Serum | Immuno chromatographic test for the confirmation and differentiation of individual antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV-1 and HIV-2) | CE Marked | Positive/Negative | LM-SERO-0028 |
| | Identification of Mycobacterium tuberculosis complex **3,4 | Positive Mycobacterial Cultures | Becton Dickinson MGIT 960 /immuno chromatographic techniques | CE Marked | Qualitative Positive/Negative | LM-IMRL-0012 |

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| 1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .01 Nucleic acid probe hybridization, CE marked commercial systems | GenoType NTM-DR Assay for subspeciation of Mycobacterium abscessus complex and detection of Macrolide and Aminoglycoside Resistance **3,4 | | Veriti Thermal Cyclers/ /GenoType Molecular assay | CE Marked | Detected / Not detected | LM-IMRL-0009 |
| | GenoType NTM-DR assay to confirm the presence of M. chimaera in mycobacterial cultures **3,4 | | Veriti Thermal Cyclers/Line probe assay | CE marked | Detected/Not detected | LM-IMRL-0009 |
| | Molecular Detection of M. tuberculosis Complex and Resistance Conferring Mutation **3,4 | Positive Mycobacterial Cultures, Respiratory Samples | Veriti Thermal Cyclers/GT Blot 48/Line Probe Assay | CE Marked | Detected/Not detected | LM-IMRL-0009 |
| | Molecular Identification of Mycobacterium Species **3,4 | Positive Mycobacterial Cultures | Veriti Thermal Cyclers/GT Blot 48/Line Probe Assay | CE Marked | Detected/Not detected | LM-IMRL-0009 |
| 1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems | AdV/hMPV/RV assay *2,3,4 | Respiratory sample | Panther Fusion / real-time PCR | CE Marked | Detected/Not Detected | LM-MOL-0052 |
| | Detection and differentiation of CPE resistance genes: bla KPC, bla NDM, bla VIM, bla OXA-48, bla IMP-1 **2,3,4 | Rectal Swabs | GeneXpert ® Instrument Systems/Real Time PCR assay for detection of Carbapenem resistance genes | CE Marked | Detected/not detected | LM-MICRO-0057 |
| | Detection and identification of Respiratory | Nasopharyngeal swabs/Combined Nasal/ Throat swab | GenMark DX ePlex ® platform/Qualitative nucleic acid multiplex | CE Marked | Detected / Not detected | LM-MOL-0047 |

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| pathogens, including SARS CoV-2 **2,3,4 | | respiratory pathogen RP2 assay. | | | |
| Detection and Quantitation of HCV RNA using the Aptima HCV Quant Dx Assay | Serum | Hologic Panther® system/nucleic acid amplification test using target capture, TMA, | CE Marked | Not Detected, < 10 IU/mL Detected but not Quantified, 10-25 IU/mL detected and quantified, 25-100,000,000 IU/mL Detected and quantified, >100,000,000 IU/mL Detected and quantified | LM-MOL-0050 |
| Detection of Adenovirus DNA **1,2,3,4 | Blood: Plasma | Applied Biosystem 7500 PCR System, | CE Marked | Quantitative: Not detected to > 800 copies/ml | LM-MOL-0033 |
| Detection of CPE genes (KPC, NDM, OXA 48 like, VIM, IMP, GES) **2,3,4 | Rectal Swabs and Isolates | Roche Light Cycler 480 II/ EntericBio RT-PCR | CE Marked | Detected or not detected | LM-MICRO-0057 |
| Detection of Cytomegalovirus DNA **1,2,3,4 | Plasma | Applied Biosystem 7500 PCR System, | CE Marked | Quantitative: Not detected to > 250 IU/ml | LM-MOL-0033 |
| Detection of Epstein Barr Virus DNA **1,2,3,4 | | Applied Biosystem 7500 PCR System | CE Marked | Quantitative: Not detected to > 800 IU/ml | LM-MOL-0033 |
| EntericBio Gastro Panel 2 for the detection of enteric pathogens including parasites - Giardia lamblia & Cryptosporidium parvum/hominis . | Faeces, Rectal Swabs, Colonic Aspirates | EntericBio realtime® Gastro panel 2 /epMotion 5070/Roche Light Cycler 480 II/ Real Time PCR | CE Marked | Detected/Not detected | LM-MICRO-0029 |
| Flu A/B/RSV assay *2,3,4 | Respiratory sample | Panther Fusion / Real-time PCR | CE Marked | Detected/Not Detected | LM-MOL-0052 |
| Molecular Detection of Hepatitis B virus **1,2,3,4 | Plasma | Hologic Panther® system/nucleic acid amplification test | CE Marked | Detected/ Not detected/ Quant <10 to 1,000,000,000 | LM-MOL-0049 |

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| | | | | IU/ml or <1.00 to > 9.00 Log10 IU/mL | |
| Molecular Detection of SARS-CoV-2 using the Aptima SARS-CoV-2 assay | Nasopharyngeal swabs/Combined Nasal/ Throat swab/BAL | Hologic Panther® system/nucleic acid amplification test using target capture, TMA, | CE Marked | Detected/Not detected | LM-MOL-0046 |
| Molecular detection of C. difficile **2,3,4 | Faeces, Rectal Swabs, Colonic Aspirates | Roche Light Cycler 480 II/ EntericBio realtime® C. difficile assay | CE Marked | Detected / Not Detected | LM-MICRO-0029, |
| Molecular detection of Carbapenamase genes (KPC, VIM, IMP, NDM, OXA-48-like) **2,3,4 | Bacterial Isolates | AUS Diagnostics Easy Plex /High Plex Real time PCR assay | CE Marked | Detected/Not detected | LM-MICRO-0056 |
| Molecular Detection of Chlamydia trachomatis **2,3,4 | Endocervical swabs, vaginal swabs, pharyngeal swabs, rectal swabs, male urethral swabs, male and female urines | Hologic Panther® system/nucleic acid amplification test using target capture, TMA, and DKA/ the Aptima CT assay | CE Marked | Detected/ Not detected | LM-MOL-0048 |
| Molecular Detection of Chlamydia trachomatis and N. gonorrhoeae **2,3,4 | | Hologic Panther® system/nucleic acid amplification test using target capture, TMA, and DKA / the Aptima Combo 2 Assay | CE Marked | Detected / Not detected | LM-MOL-0048 |
| Molecular Detection of CSF pathogens (Bacterial, Viral & Fungal) using the BIOFIRE Filmarray ME Panel. | Cerebrospinal fluid | BIOFIRE® FILMARRAY® TORCH Instrument, multiplex PCR system | CE Marked | Detected/Not Detected | LM-MICRO-0061 |
| Molecular detection of Influenza A/B **2,3,4 | Nasopharyngeal swabs/ Nasal/ Throat swab | Cepheid GeneXpert System / automated, multiplex , real time RT-PCR assay. | CE Marked | Detected / Not detected | LM-MOL-0041 |
| Molecular detection of M. tuberculosis Complex and | Positive Mycobacterial Cultures | Cepheid GeneXpert, System multiplex real time RT PCR | CE Marked | Detected /Not detected. | LM-IMRL-0013 |

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| | Rifampicin Resistance **2,3,4 | | | | | |
| | Molecular Detection of N. gonorrhoeae **2,3,4 | Endocervical swabs, vaginal swabs, pharyngeal swabs, rectal swabs, male urethral swabs, male and female urines | Hologic Panther® system/nucleic acid amplification test using target capture, TMA, and DKA/ the Aptima GC assay | CE Marked | Detected/ Not detected | LM-MOL-0048 |
| | Molecular detection of SARS-CoV-2 **2,3,4 | Respiratory samples (nose/throat swabs, bronchoalveolar lavages, nasopharyngeal aspirates, endotracheal aspirates) | Applied Biosystems AB 7500 / Mutaplex Coronavirus Real time RT-PCR | CE Marked | Detected / Not detected | LM-MOL-0043 |
| | Molecular detection of SARS-CoV-2 , Influenza A, Influenza B, RSV **2,3,4 | Nasopharyngeal swabs/Combined Nasal/ Throat swab | Cepheid GeneXpert System / automated, multiplex real-time, (RT-PCR) | CE Marked | Detected / Not detected | LM-MOL-0045 |
| | Molecular Investigation of faeces specimens for enteric pathogens **2,3,4 | Faeces, Rectal Swabs, Colonic Aspirates | Roche Light Cycler 480 II/ EntericBio realtime® Gastro panel 1 | CE Marked | Detected / Not Detected | LM-MICRO-0029, |
| | Paraflu assay *2,3,4 | Respiratory sample | Panther Fusion / Real-time PCR | CE Marked | Detected/Not Detected | LM-MOL-0052 |
| 1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .04 Nucleic acid amplification tests, in house developed assays | Detection and Characterisation of Microbial DNA/RNA (pvl/mec) | Bacterial Isolates | Applied Biosystems 7500 PCR / Real Time PCR | In House Developed | Detected / not detected. | LM-MRSA-0012 |
| | Detection and Characterisation of Microbial DNA/RNA in MRSA (spa typing) | | MiniAmp Thermal Cycler | In House Developed | N/A | LM-MRSA-0011 |
| | Detection of Hepatitis E RNA | Serum, Plasma | Applied Biosystems AB 7500 Fast / Real-Time PCR | In-House Developed | Detected, Not Detected | LM-MOL-0037 |

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| | Detection of LGV DNA | Rectal Swabs | Applied Biosystem 7500 PCR System/Real Time PCR | In house developed | Detected/ Not detected | LM-MOL-0036 |
| | Detection of Varicella-zoster DNA | Anogenital, Dermal, Ocular, Oral region swabs | Applied Biosystem 7500 PCR System, / Real Time PCR | In house developed | Qualitative ; Detected / Not detected. | LM-MOL-0034 |
| | Real time PCR for the detection of genes associated with linezolid resistance | Staphylococci and Enterococci isolates | AB7500 | In house Assay | Positive/ negative | LM-MRSA-0017 |
| 1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .05 Nucleotide sequencing & analysis | cgMLST and whole genome sequencing identification, lineage calling and relatedness analysis of bacterial isolates | | Illumina MiSeq | CE Marked | Lineage identification & relatedness analysis | LM-MRSA-0015 |
| | cgMLST and whole genome sequencing identification, lineage calling and relatedness analysis of Mycobacterium tuberculosis Complex | Mycobacterium Isolates | Illumina (MiniSeq and MiSeq) platforms / WGS | CE Marked | Lineage identification & relatedness analysis | LM-IMRL-0020 |
| | Confirmation of Pyrazinamide Resistant Mycobacterium tuberculosis using DNA Sequencing Methods | Positive Mycobacterial Cultures | Veriti Thermal Cycler/AB3500 Genetic Analyser | In house developed | N/A | LM-IMRL-0018 |
| | Confirmation of Rifampicin resistance by investigating variants in the rpoB gene using sequencing methods | | Veriti Thermal cycler/AB3500 Genetic Analyser | In house developed | N/A | LM-IMRL-0019 |
| | Identification of Non Tuberculosis Mycobacteria by Sequencing the 65kd | | Veriti Thermal Cyclers/GT-Blot 48 | In house developed | N/A | LM-IMRL-0015 |

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| | Shock Protein (hsp65) Gene | | | | | |
| | Speciation within the MAC Complex using 16S and ITS Sequencing | | Veriti Thermal Cyclers/GT-Blot 48 | In house developed | N/A | LM-IMRL-0014 |
| 1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems | Identification of yeast **3,4 | Yeast isolate | Biomerieux Vitek 2 XL / VITEK 2 yeast identification card (YST) | CE Marked | N/A | LM-MICRO-0005. |
| | Identification of Cultured Bacteria **3,4 | Bacterial Isolates | Biomerieux Vitek 2 XL | CE Marked | N/A | LM-MICRO-0004, 06, 07, 08, 09, 10, 11, 13, 14, 15, 16, 19, 20, 23, 24, 25, 26, 27, 28, 29, 32, 33, 37, 43, 48, 52, LP-MICRO-0186 |
| | Identification of S. pneumoniae **2,4 | Bacterial Isolate | Manual /Optochin disc | CE Marked | Positive: Zone of inhibition; Negative: No zone of inhibition | LM-MICRO-0036 |
| | Tube Coagulase **4 | Bacterial Isolates | Manual/Test Kit | CE Marked | Positive/Negative | LM-MRSA-0002 |
| 1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .03 Identification of fungi by microscopic morphology | Microscopic identification of fungal isolates **3,4 | Fungal Isolates | Microscope/ Manual lactofuschin stain | CE marked | N/A | LM-MICRO-0022, 41 |
| 1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy | Rapid method for microorganism identification from microbial cultures **4 | Bacterial Isolates | Vitek MS/Matrix-assisted laser desorption/ionization | CE Marked | N/A | LM-MICRO-0004, 06, 07, 08, 09, 10, 11, 13, 14, 15, 16, 19, 20, 23, 24, 25, 26, 27, 28, 29, 32, 33, 37, 43, 48, 52, LP-MICRO-0195 |
| 1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly | Antimicrobial susceptibility for Carbapenemase resistant | Bacterial Isolate | Automated: Vitek 2XL/MIC, Manual: Gradient MIC, Disc diffusion | CE Marked | S/I/R | LM-MICRO-0003,59 |

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| growing aerobes) - .01 Anaerobes | Enterobacteriaceae (CPE) **1,4 | | | | | |
| | Antimicrobial susceptibility for Vancomycin resistant Enterococci **1,4 | | Automated: Vitek 2XL/ MIC, Manual: Gradient MIC | CE Marked | S/I/R | LM-MICRO-0003,59 |
| | Antimicrobial susceptibility testing - automated **1,2,4 | Bacterial Isolates | Biomerieux Vitek 2XL | CE Marked | S/I/R | LM-MICRO-0003 |
| | Detection of Beta Lactamase **4 | | Manual/Chromogenic detection of enzyme | CE Marked | Positive/Negative | LM-MICRO-0003 |
| | Methicillin Resistance Detection By Disk Diffusion **1,2,4 | | Manual/ Zone measurements | CE Marked | S/I/R | LM-MRSA-0002 |
| | Minimum Inhibitory Concentrations using Gradient MIC in MRSA isolates **1,2,4 | | Manual/Gradient MIC | CE Marked | S/I/R | LM-MRSA-0005 |
| | Specialised Antibiotic Procedures for Glycopeptide Resistance Investigation **1,2,4 | | Manual/MIC Broth Dilution/Gradient MIC/Growth or no Growth | CE Marked | S/I/R | LM-MRSA-0006, 07 |
| | Susceptibility Testing (Disc Diffusion) **1,2,4 | | Calipers/Manual/Zone Measurements | CE Marked | S/I/R | LM--MICRO-0003, LM MRSA-0003 |
| | Susceptibility Testing (MIC Method) **1,2,4 | | Manual/MIC using Gradient MIC Method) | CE Marked | S/I/R | LM-MICRO-0003 |
| 1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .02 Mycobacteria | New and re purposed anti-TB agents (bedaquiline, clofazimine, delamanid, linezolid and levofloxacin) for susceptibility testing Of M. tuberculosis complex isolates | Mycobacterium Isolates | BACTEC MGIT 960 system/Susceptibility testing: proportional method at a critical concentration | CE Marked | Susceptible / Resistant | Std.ref: World Health Organization. Technical manual for drug susceptibility testing of medicines used in the treatment of tuberculosis. World Health Organization; WHO/CDS/TB/2018.24. SOP:LM-IMRL-006 |

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| | Susceptibility Testing of First and Second Line Anti-tuberculosis Drugs **1,2,4 | Positive Mycobacterial Cultures | Becton Dickinson Bactec MGIT 960 | CE Marked | S/I/R | LM-IMRL-0006 |
| 1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .03 Yeasts | Yeast One Sensititre **1,2,4 | Fungal Isolate | Manual/Antifungal susceptibility test | CE Marked | S/I/R | LM-MICRO-0039 |
| 1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .04 Filamentous fungi | Antifungal susceptibility **1,2,4 | | Manual/Antifungal Susceptibility testing (Gradient MIC) | CE Marked | S/I/R | LM-MICRO-0039 |
| 1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .02 Enzyme immunoassay, using CE marked commercial systems | Detection of IgM specific Antibodies to Hepatitis E **2,3,4 | Serum | Manual/EIA Assay | CE Marked | Qualitative : Positive/Negative | LM-SERO-0023 |
| | Detection of IgM specific Antibodies to Treponema pallidum **2,3,4 | Blood | Manual/EIA using the Captia NMT Syphilis IgM | CE Marked | Qualitative : Positive/Negative | LM-SERO-0006 |
| | Enzyme immunoassay for the detection of Antibodies to Human Hepatitis C Virus **2,3,4 | | Manual/EIA using the INNOGENETICS INNO-LIA Syphilis Score | CE Marked | Qualitative Positive/Negative | LM-SERO-0018 |
| | Qualitative detection of HIV p24 antigen, HIV-1 antibody & HIV-2 antibody **2,3,4 | Blood: Plasma, Serum | BioMerieux VIDAS HIV DUO Ultra/ Enzyme Linked Fluorescent Assay ELFA | CE Marked | Qualitative Negative , Positive | LM-SERO-0026 |

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| 1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .04 Line immunoassay, using CE marked commercial systems | Detection of antibodies against Treponema pallidum **2,3,4 | Blood | Manual/Line Blot Line Immuno Assay | CE Marked | Intensity of Antigen lines: Negative to +4 | LM-SERO-0009 |
| 1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .07 Chemiluminescent microparticle immunoassay, using CE marked commercial systems | Qualitative detection of Anti HB core antibody **2,3,4 | Serum | Abbott Alinity i / chemiluminescent microparticle immunoassay (CMIA) | CE Marked | Detected / Not Detected | LM-SERO-0027 |
| | Qualitative detection of Anti-HCV antibody **2,3,4 | | Abbott Alinity i / chemiluminescent microparticle immunoassay (CMIA) | CE Marked | Detected / Not Detected | LM-SERO-0027 |
| | Qualitative detection of EBV-EBNA-1 IgG **2,3,4 | | Abbott Alinity i / chemiluminescent microparticle immunoassay (CMIA) | CE Marked | Detected / Not Detected | LM-SERO-0027 |
| | Qualitative detection of HAV IgG **2,3,4 | | Abbott Alinity i / chemiluminescent microparticle immunoassay (CMIA) | CE Marked | Detected / Not Detected | LM-SERO-0027 |
| | Qualitative detection of HAV IgM **2,3,4 | | Abbott Alinity i / chemiluminescent microparticle immunoassay (CMIA) | CE Marked | Detected / Not Detected | LM-SERO-0027 |
| | Qualitative detection of HBsAg **2,3,4 | | Abbott Alinity i / chemiluminescent microparticle immunoassay (CMIA) | CE Marked | Detected / Not Detected | LM-SERO-0027 |
| | Qualitative Detection of Anti HB core IgM using the Alinity i system | Serum | Abbott Alinity i / chemiluminescent microparticle immunoassay (CMIA) | CE marked | Positive/Negative | LM-SERO-0027 |

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|---|--|--------------|--|-----------|---|---------------|
| | Qualitative Detection of Anti-HBe using the Alinity i system | Serum | Abbott Alinity i / chemiluminescent microparticle immunoassay (CMIA) | CE marked | Positive/Negative | LM-SERO-0027 |
| | Qualitative detection of EBV VCA IgG **2,3,4 | | Abbitt Alinity i / Chemiluminescent Microparticle Immunoassay (CMIA) | CE Marked | Detected / Not Detected | LM-SERO-0027 |
| | Qualitative detection of EBV VCA IgM **2,3,4 | | Abbott Alinity i / Chemiluminescent Microparticle Immunoassay (CMIA) | CE Marked | Detected / Not Detected | LM-SERO-0027 |
| | Qualitative Detection of HBeAg using the Alinity i system | | Abbott Alinity i / chemiluminescent microparticle immunoassay (CMIA) | CE marked | Positive/Negative | LM-SERO-0027 |
| | Qualitative detection of HIV Ag/Ab **2,3,4 | | Abbott Alinity i / chemiluminescent microparticle immunoassay (CMIA) | CE Marked | Detected / Not Detected | LM-SERO-0027 |
| | Qualitative detection of Syphilis Ab **2,3,4 | | Abbott Alinity i / chemiluminescent microparticle immunoassay (CMIA) | CE Marked | Detected / Not Detected | LM-SERO-0027 |
| | Quantitative detection of Anti HBs **2,3,4 | | Abbott Alinity i / chemiluminescent microparticle immunoassay (CMIA) | CE Marked | Detected (mIU/mL) / Not Detected | LM-SERO-0027 |
| 1029 Miscellaneous - .99 Miscellaneous tests | Detection of β -1-3 Glucan **1,2,3,4 | Blood: Serum | Biotek ELx808 Microtitre Plate Reader/ Protease zymogen-based colorimetric assay | CE Marked | Semi Quantitative. Negative: <60pg/ml, Positive: >80pg/ml, Indeterminate: 60-80pg/ml | LM-MICRO-0058 |

The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratory's approved and documented procedures.

Note 1 - Range may be extended for the test

Note 2 – New parameters/tests may be added

Note 3 – New matrices may be added

Note 4 – Changes to equipment/kits where the underlying methodology does not change

For further details please refer to the laboratory's 'List of flexible scope changes', available directly from the laboratory.

